

**iMNS**

**MEDACTA NAVIGATION  
SYSTEM**

**SURGICAL  
TECHNIQUE**

**GMK**

**v 4.4.0 and up**

**Ref: 99.36.12US rev.02**

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of physician.

Distributed by MEDACTA USA, Inc, 4725 Calle Quetzal Unit B Camarillo, CA 93012 **1 (800) 901-7836.**

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## **SYMBOLS**

Throughout the surgical technique you will find the following symbols:



The descriptions in the “*Option*” boxes are referred to first generation GMK instruments.



The descriptions in the “*MSS*” boxes are referred to instruments suitable for muscle sparing approaches.

## **CAUTION**

BEFORE USING THE MEDACTA iMNS™ NAVIGATION SYSTEM, CAREFULLY READ THROUGH THE MANUALS PROVIDED WITH THE SYSTEM AND THE SURGICAL TECHNIQUES RELATED TO THE SURGERY TO BE PERFORMED. THE USER IS RESPONSIBLE FOR ANY DAMAGE OR MALFUNCTIONING CAUSED BY IMPROPER USE OF THE iMNS™ SYSTEM OR OF ANY OF ITS COMPONENTS.

This manual illustrates the operation of the navigation software produced by MEDACTA for the specific application described herein. This manual applies only to the GMK Knee application.

This manual describes the Computer Assisted surgical technique of the GMK and describes the use of navigation-related instruments. The user is required to be familiar with the conventional GMK surgical technique.

The information contained in this manual and the product to which it refers may be modified by MEDACTA without giving prior notice.

Note: Most of the numerical values in the navigation program are expressed in millimeters or degrees.

## GENERAL DESCRIPTION

### 1. INTENDED USE

The iMNS™ Medacta Navigation System is intended to be used to support the surgeon during specific orthopaedic surgical procedures by providing information on bone resections, instrument and implant positioning during joint replacement.

The iMNS™ Medacta Navigation System provides computer assistance to the surgeon based on anatomical landmarks and other specific data obtained intra-operatively that are used to place surgical instruments.

Examples of surgical procedures include but are not limited to:

- Total knee replacement
- Minimally invasive total knee replacement



**The MEDACTA iMNS™ system does not provide information of diagnostic nature.**

**Use the iMNS™ system only with the equipment specifically supplied or approved by MEDACTA.**

**The iMNS™ navigation system must be cleaned and disinfected immediately after use by qualified personnel.**

**Clean and disinfect the instruments supplied in trays to be used with the iMNS™ navigation system before sterilization following the "Recommendations for the Decontamination and Sterilization of Medacta International SA Reusable Orthopaedic Devices", available from the company's website [www.medacta.com](http://www.medacta.com) or by calling 1 (800) 901-7836.**

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This manual illustrates the *software* operating modes and provides the necessary instructions for their proper and safe use.



**The system shall be used exclusively by suitably trained personnel.**

**Studying this manual is an integral part of the training process.**

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**Should any part of the manual not be clear, please contact the specialized MEDACTA staff for help.**

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**The GMK v.4.4.0 application whose operating modes are described in this manual has been developed and produced to be used exclusively in conjunction with GMK equipment.**

**To properly use the instruments in association with the iMNS™ navigation system, please refer also to the GMK Surgical Technique.**

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**The iMNS™ system shall not be used to perform surgeries other than the ones indicated in the surgical techniques enclosed to this manual.**

**Do not use the iMNS™ system in the presence of sources or reflectors of intense infrared radiation, as under these conditions the acquisition system is unable to work properly. In addition, avoid exposing the acquisition system to direct daylight.**

**In case of knee operations, adequate mobility of the corresponding hip joint is an essential requirement for the effective use of the iMNS™ system.**

**It is essential to always bear in mind all the warnings related to the surgery to be performed.**

---

### **1.1. Contraindications**

Progressive local or systemic infection

Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable

Severe instability secondary to advanced destruction of osteocondral structures or loss of integrity of the lateral ligament

Anatomic abnormalities preventing accurate landmarks acquisition or kinematic registration

Any condition of the tibia or the femur preventing a stable fixation of the necessary reference arrays

Any condition of the tibia and the femur so that the insertion of bicortical pins holding the reference arrays represents an unacceptable risk of stress fracture

Patient characteristics that, in the opinion of the surgeon, make the use of computer assisted total knee replacement inappropriate

Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications. It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

### **1.2. Complications**

If the MEDACTA iMNS™ system is improperly used, the following complications may arise among others:

- Infection
- Incorrect implant positioning
- Failed recovery of the articular functionality

Refer to the respective package insert for the applicable implant for information about complications.



Like all electrical devices, the iMNS™ MEDACTA navigation system may be subject to malfunction due to improper use or to technical reasons. It is always possible to complete the surgery with the aid of the standard equipment, which must necessarily be available in the operating theatre.

As an electronic device, iMNS™ system should not be put in direct contact with flammable materials, such as anesthetics, solvents, detergents, gases. In addition, avoid exposing the acquisition system to direct daylight.

Although the iMNS™ Navigation System has been tested and declared fully satisfying the electromagnetic compatibility requirements indicated in the standards EN 60601-1-2 2nd ed., radio communication devices, including portable ones, may interfere with the iMNS™ system reducing its accuracy.

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## 2. INSTALLATION



For proper installation and maintenance of the MEDACTA iMNS™ navigation system, refer to the specific hardware user manual.

Use the iMNS™ system only with the equipment specifically supplied or approved by MEDACTA.

Prior to every surgery, make sure that the instruments have been properly sterilized and that they are in such conditions as to adequately perform their function. The instruments for non-navigated surgery should also be available.

Clean and disinfect the instruments before sterilization.

Before sterilizing the reference arrays, remove the markers from their supports. **THE MARKERS ARE MEANT FOR ONE-TIME USE:** They are provided sterile. Do not sterilize them, do not reuse them.

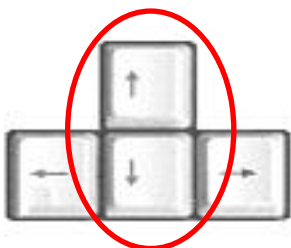
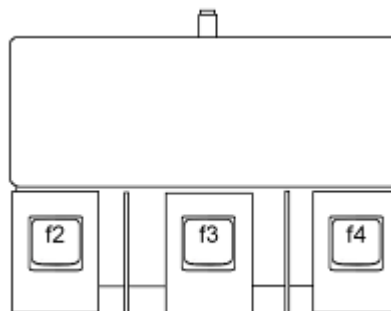
Re-sterilizing and re-utilizing the passive markers may compromise the infrared reflective properties.

The user is responsible for damages to components caused by incorrect sterilization.

---

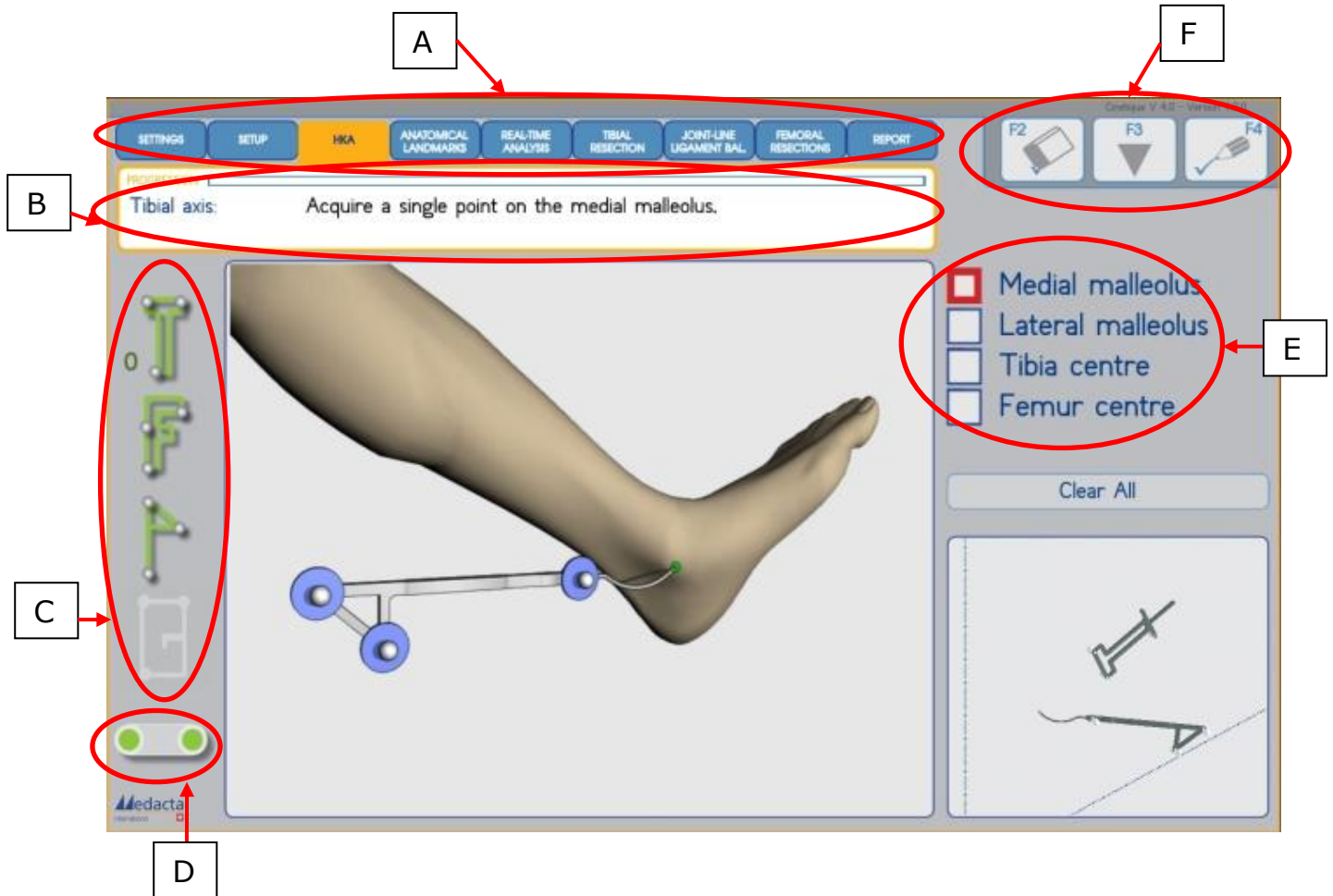
### 3. CONTROLS

iMNS™ navigation system is controlled by means of 3 pedals : the keyboard is used in some specific circumstances only. Keys F2, F3 and F4 can always be used instead of left, middle and right pedal, respectively.



Up and down « arrow » keys can also be used to move the cursor (red rectangle contouring the currently selected control) up and down.

#### 4. USER INTERFACE



##### A: WORKFLOW INDICATOR

Indicates the overall navigation workflow and the position of the current step (yellow).

##### B: PROGRESSION BAR and INSTRUCTIONS

The progression bar indicates whether the minimum necessary information to move to the next screen has been provided to the navigator: if the operator has not yet entered any of the necessary information, the bar is completely white. It progressively changes to yellow as information is added. When the bar is completely yellow, it means that the information provided is sufficient and that it is possible to go to the next navigation step.

##### C: REFERENCE ARRAYS

Icons are green if the corresponding arrays are visible, red if they are not visible and gray if they are not needed in the current step. A number displaying the accuracy appears next to the F and T array icon when stability is being tested.

#### D: CAMERA

The icon is normally green. It turns to red when the camera is off or not working properly, yellow in case some problem with data transfer arises (e.g. unplugged data connector).

#### E: ACQUISITIONS

The acquisition to be performed is highlighted by the cursor. When an acquisition is done, a tick (☑) appears in the box.

#### F: NAVIGATION BOX

Indicates the operations performed by pressing each pedal.

When the Navigation box is selected it is possible to move to the previous (F2) or the next (F4) navigation step.

Items in E and F can be selected by the user. A red contour highlights the currently selected item.



**Keeping the central pedal pressed for more than 3 tenths (0.3) of a second, moves the cursor back to the Navigation Box.**

---

## 5. ICONS IN THE NAVIGATION BOX

### 5.1. CONTROLS

#### NAVIGATION BOX SELECTED

LEFT PEDAL



Back to previous screen

MIDDLE PEDAL



Scroll down selection

RIGHT PEDAL



Go to next screen

#### ANOTHER BUTTON SELECTED

LEFT PEDAL



Delete selected data

MIDDLE PEDAL



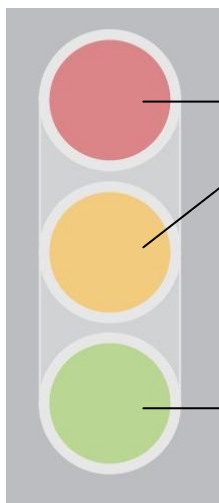
Scroll down selection

RIGHT PEDAL



Confirm/Perform operation

## 6. ACCURACY INDICATOR



Accuracy is not satisfactory: repeat the acquisition

Accuracy is good. Proceed to the next step

## 7. SHORTCUTS

F1 = Screen capture (both an acoustic signal and a message on screen will confirm the operation)

F5 = List of the shortcuts

F6 = Navigation settings

F7 = Camera positioning

F8 = F & T Confidence test

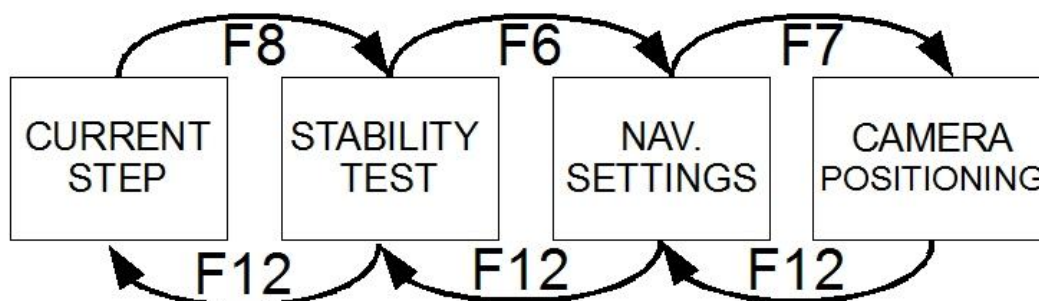
F9 = Pre-surgery analysis

F11 = screenshots slide show

F12 = Back to current step (the navigation step in use when the shortcut was selected)

Shortcuts can be also activated in sequence.

Example:



## 8. REFERENCE ARRAYS

### 8.1. Preparing the reference arrays

The system works with four different reference arrays, also known as *rigid bodies*:



Figure 1: T-shaped reference array for the tibia



Figure 2: F-shaped reference array for the femur



Figure 3: G-shaped reference array for the cutting guides



Figure 4: P-shaped reference array: pointer

T: T-shaped reference array, used to identify the position of the tibia of the patient.

F: F-shaped reference array, used to identify the position of the femur of the patient.

P: P-shaped reference array (*pointer*), used to perform all the acquisitions of the anatomical references during navigated surgery.

G: G-shaped reference array, used to identify the position of the different cutting guides.

The passive markers, disposable IR reflecting balls, must be assembled on the reference arrays before each surgery. For the assembly, maintenance and operating procedures see the appropriate paragraph in the hardware user manual.



**Blue disks must be assembled on G-shaped and P-shaped arrays. Using the G-array or the pointer without the blue disks in place will lead to unpredictable results.**

## 8.2. Installing the reference arrays

### 8.2.1. Easy-Clip™ option [Ref.no. 33.22.0065]

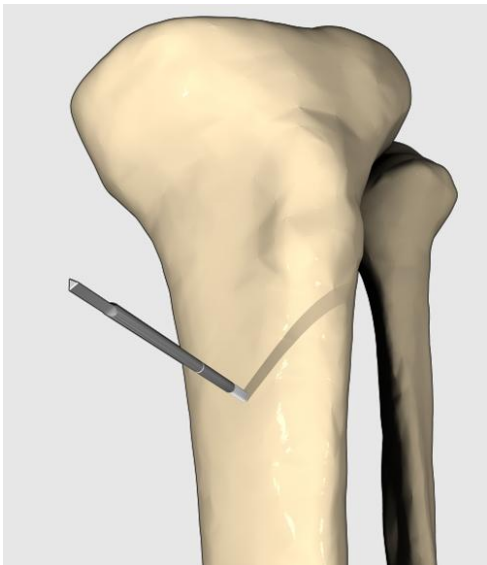
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**The side of the reference array bearing the passive markers must face the camera.**

---

For proper positioning of the F- and T-shaped reference arrays respectively on the femur and the tibia of the patient, follow the instructions below.



Simulate the placement of the tools you will use during the surgery, to make sure that they will not interfere with the reference arrays.

The pins holding the reference arrays can be positioned either percutaneously or inside the incision according to the needs and to the different surgical techniques. Usually, it is preferable to insert them in the antero-medial aspect of the bone.

Having selected the appropriate location, insert the first pin into the bone.



**Secure the pins medially with respect to the anatomical axis of the tibia in order to prevent any conflicts with the alignment rod that can be used to control the tibial cutting guide positioning.**

---



**Threaded pins must be inserted until the second bone cortex is reached in order to assure the maximum hold in the bone.**

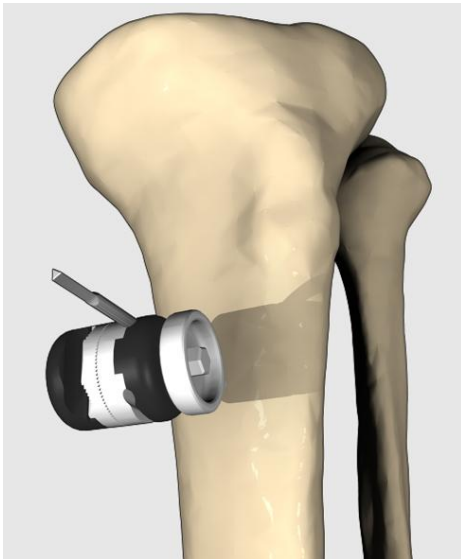
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Open the Easy-CLIP™ hinge by unscrewing it.



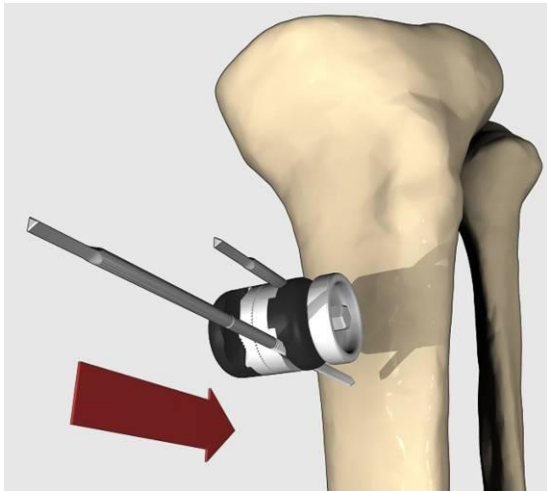
**Carefully unscrew the Easy-CLIP™ hinge without forcing it beyond the limit.**



Fit the Easy-CLIP™ on the pin already introduced in the bone, orient the hinge so that the locking knob is facing opposite to the camera, and use it as a guide to insert the second pin through the proper groove.

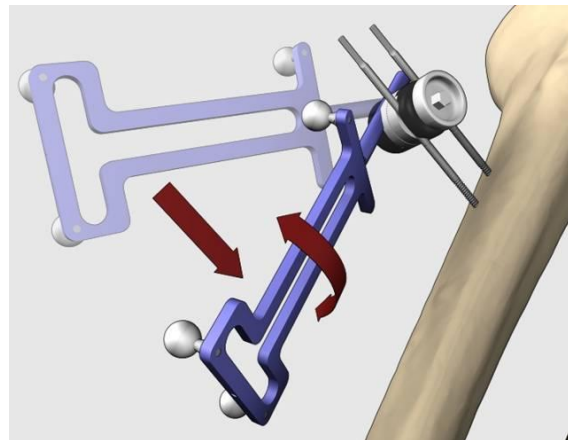


**When fitting Easy-CLIP™ hinge on the first pin it is advisable to use the groove closer to the knee joint (see picture) and leave the one farther from the joint to guide the insertion of the second pin. Before inserting the pin, make sure that the line connecting the two pin holes is parallel to the mechanical axis.**

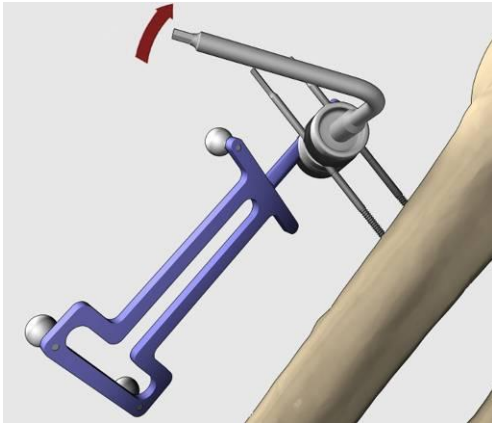


Slide the hinge on the two pins to move it about 5 mm from the skin.

Once the second pin has been introduced, insert the reference array in the dedicated hole, rotate it around the axis of the hinge so that it is approximately parallel to the mechanical axis (see figure) and orient it towards the camera.



**Make sure that the T and F reference arrays are parallel to the sagittal plane or slightly facing anteriorly.**



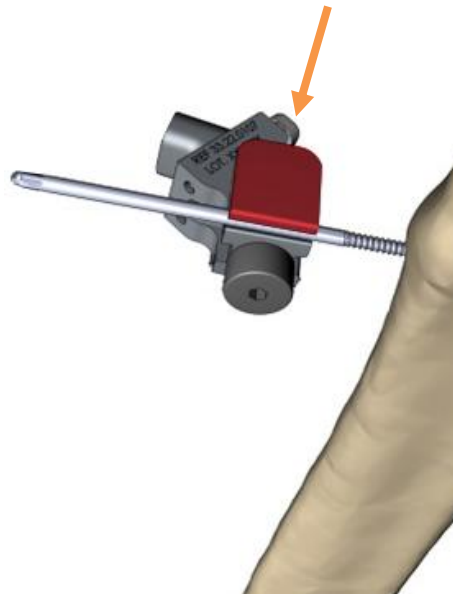
Using the special Allen wrench, tighten Easy-CLIP™ to lock the entire assembly.



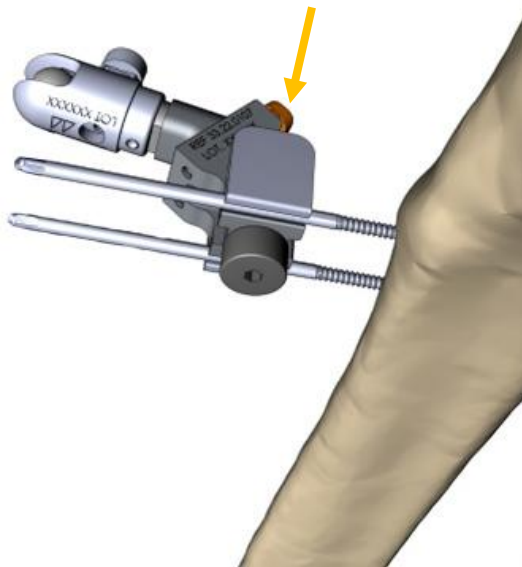
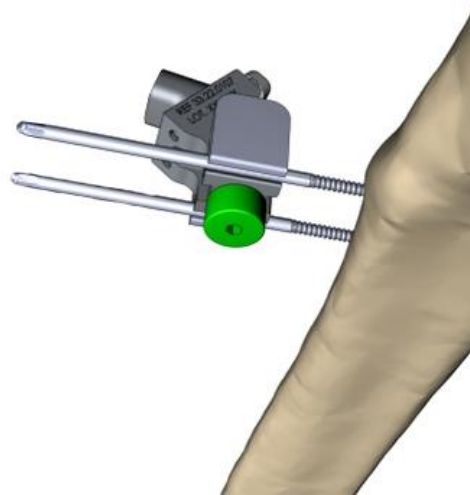
**Make sure that the mechanical assemblies have been sufficiently tightened and that none of its parts are loose. Should any of the reference arrays change position during the surgery, it would invalidate the exactness of the data and it will be necessary to abort navigation or repeat the acquisition procedure from the start.**

### 8.2.2. Pins locking clamp option [ref.no. 33.22.0107]

The T-shaped and F-shaped arrays can alternatively be secured on bones using the hinge in figure. Insert the first pin, mount the hinge on it pushing the lever (red in figure) taking care that the release button (indicated in figure) is facing the patient, finally measure the distance where to insert the second pin using the hinge itself.

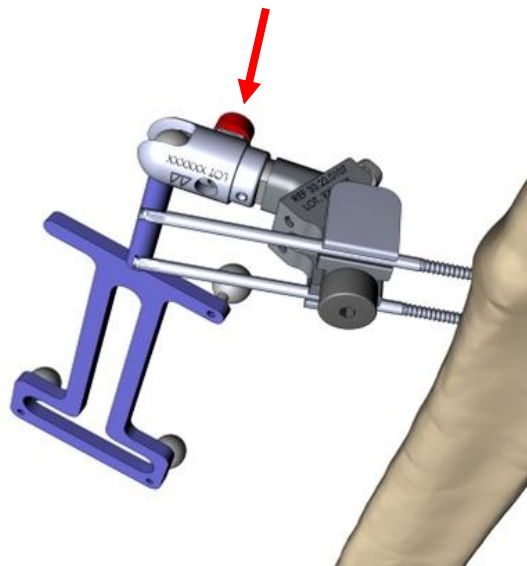


After both pins have been inserted, the locking screw (see figure, in green) must be tightened to prevent any movements.



Insert the head for rigid body (ref.no. 33.22.0108) into the dedicated slot on the clamp (only one orientation is allowed) by pressing the release button (see figure, in yellow).

Insert the reference array into the ball socket, orient it parallel to the bone diaphysis, facing the camera and slightly anterior. Once the positioning is satisfying, tighten the screw (see figure, in red) to fix the position.



This fixation system allows the reference array to be removed during the surgery, when not needed.



**Do not remove the reference array when acquisitions are ongoing.**

To release the reference array, push the release button and extract it keeping it assembled with the support.



**Do not directly pull the array when removing it.**

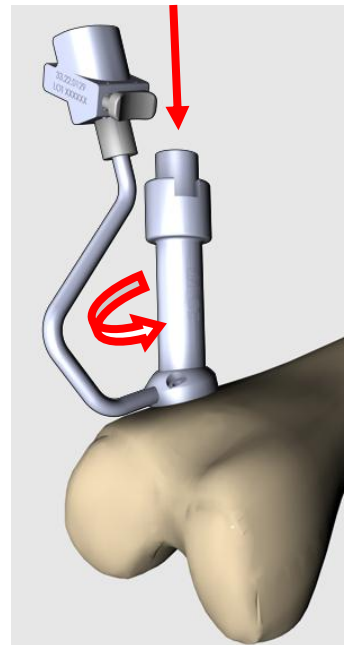


**After reconnecting a reference array on the clamp, it is recommended to perform a confidence test before proceeding with navigation.**

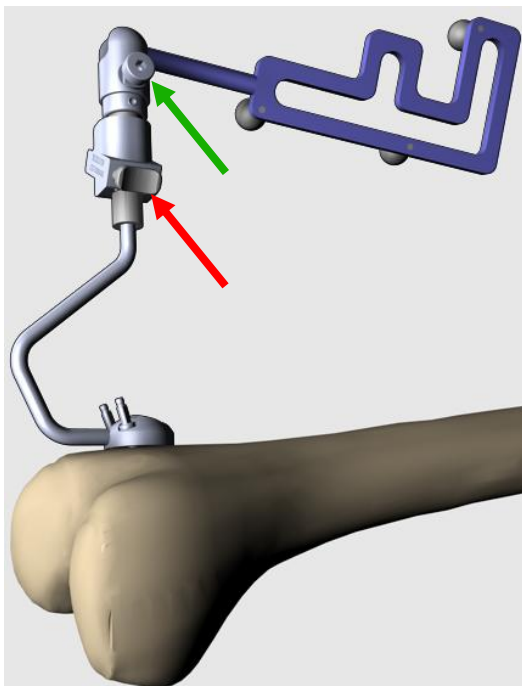
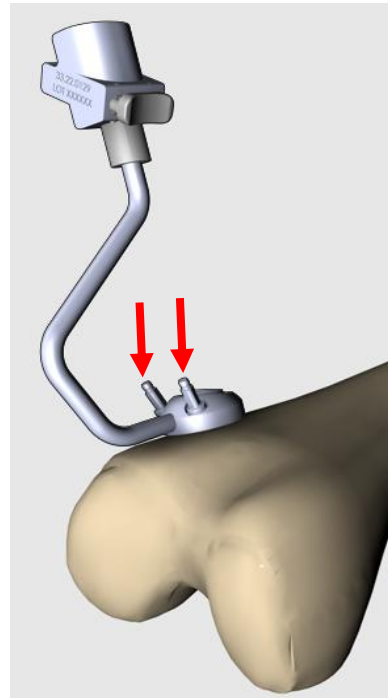
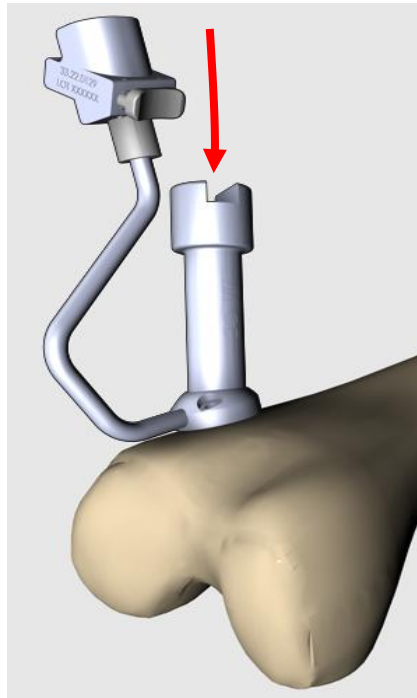
### **8.2.3. Femoral holder option [ref.no. 33.22.0129]**

The F-shaped array can alternatively be secured on femur using the femoral holder as shown (ref.no. 33.22.0129).

Position the femoral holder on the medial distal anterior condyle (*pic. aside, left femur*), connect the screw guide (ref.no. 33.22.0130), insert the sleeve for the 3.2 mm drill (ref.no. 33.22.0131) and perform the hole for the fixing screw with the dedicated 3.2 mm drill.



Remove the 3.2 mm drill sleeve and insert into the screw guide the fixing screw (*red arrow in figure below, left*) by mean of a dedicated screwdriver. Two additional sword pins (ref.no. 33.24.0096) can be used to further stabilize the holder (*red arrows in figure below, right*).



Insert the head for rigid body (ref.no. 33.22.0108) into the dedicated slot on the femoral holder (only one orientation is allowed) by pressing the release button (*red arrow in fig. left*). Insert the reference array into the ball socket, orient it parallel to the bone diaphysis, facing the camera and slightly anterior. Once the positioning is satisfying, tighten the screw (*green arrow in fig. left*) to fix the position.

This fixation system allows the F-shaped array to be removed during the surgery, when not needed.



**Do not remove the reference array when acquisitions are ongoing.**

To release the reference array, push the release button and extract it keeping it assembled with the support.



**Do not directly pull the array when removing it.**



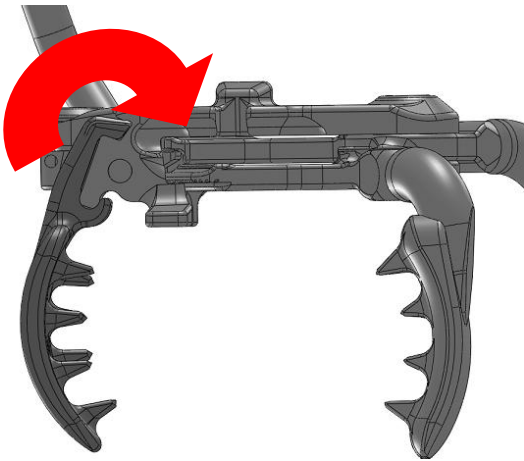
**After reconnecting the F-shaped array on the femoral holder, it is recommended to perform a confidence test before proceeding with navigation.**

#### **8.2.4. Femoral clamp option [ref.no.02.06.10.0069/02.06.10.0070]**

The femoral clamp allows to perform the femoral cuts without using any pin to fix the F-array on the femoral bone.

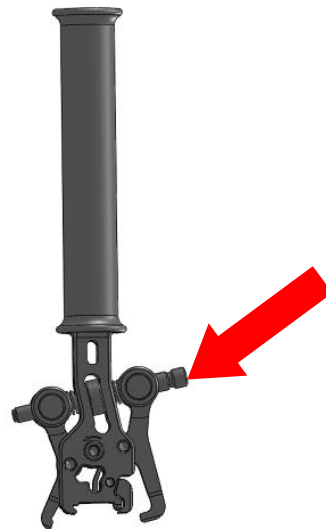
Select the clamp version depending on the side operated (left or right) and chose the medial jaw version depending on the femur size (large or small) and leg side (left or right). Engage the medial jaw on the main body of the femoral clamp as shown in picture.



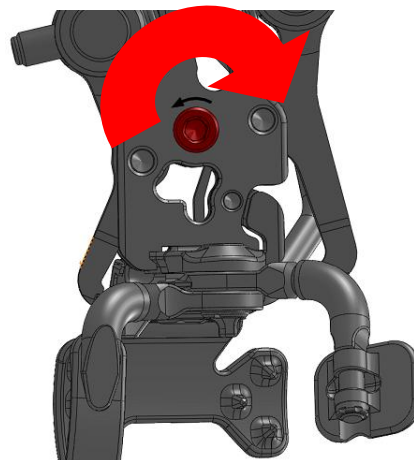
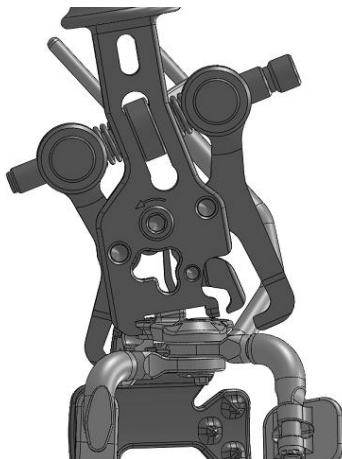


Rotate the medial jaw and clip it on the main body of the clamp.

Open the bone plier unscrewing the corresponding screw (picture right, red arrow).

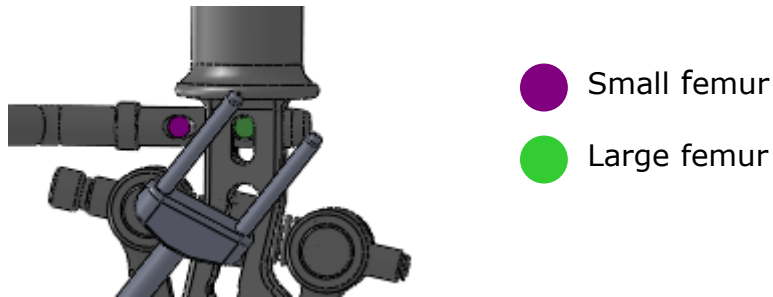


Engage the bone plier on the femoral clamp (pic. below, left) and rotate it on the clamp (pic. below, right). Lock the connection by turning the corresponding screw (pic. below right, in red) in the same sense as indicated by the marked arrow.



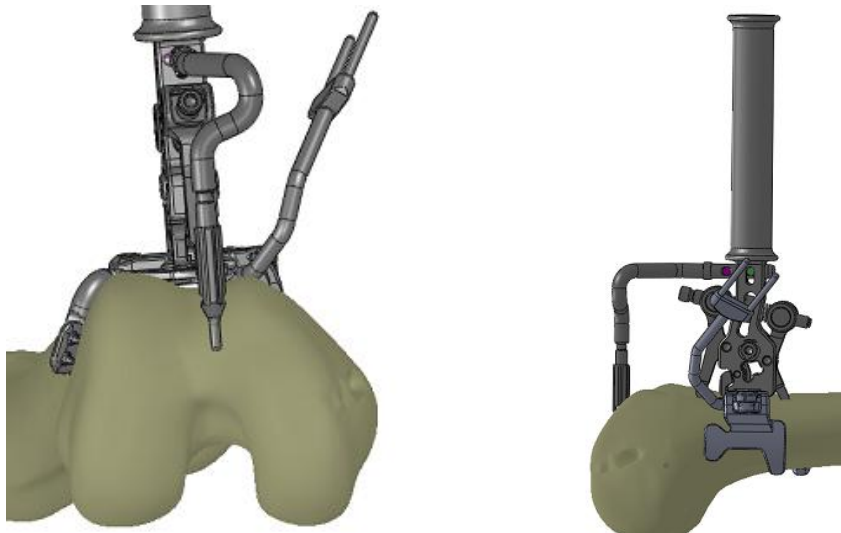
The bone plier is then used to position the clamp on the femur .

Insert the Whiteside's reference rod into the corresponding hole located on the plier. Two positions are available, depending on the femur size (small or large):



The position of the clamp on the femur is determined depending on:

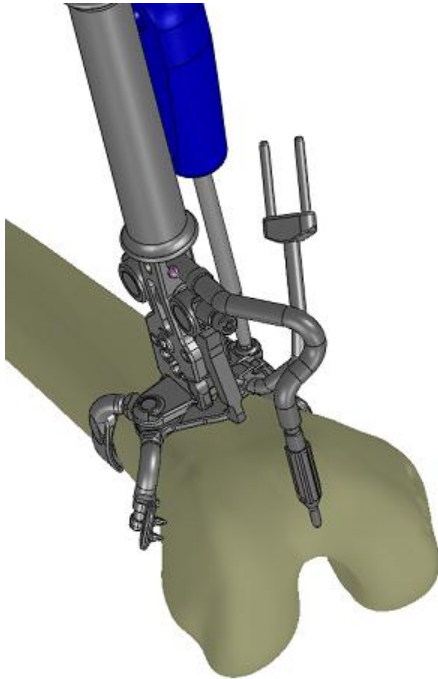
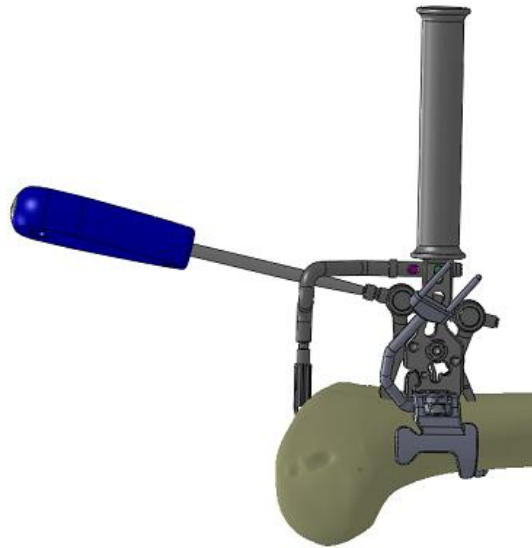
- rotational alignment: align the Whiteside's rod along the Whiteside's line direction (pic. below, left)
- proximal/distal position: put the Whiteside's rod in contact with the intercondylar notch (pic. below, right).



Lock the two plier jaws by screwing the corresponding screw on the plier.

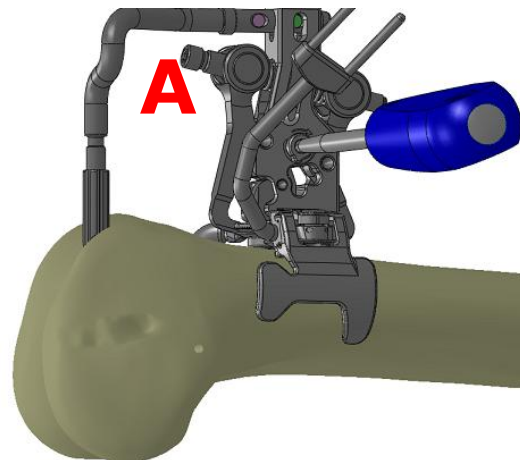


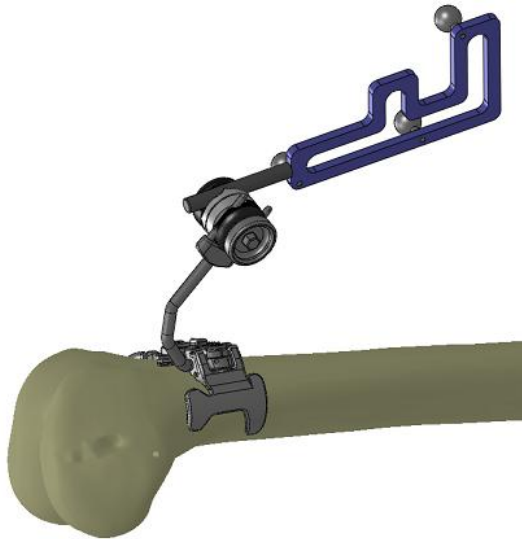
**Do not over tight the plier screw. Over tightening may cause bone breakage.**



Fix the jaws position by turning the medial screw on the clamp.

Slightly unscrew the screw A (see pic. right) then unlock the locking screw (turn it in the opposite sense as previously done) and finally remove the plier from the clamp.

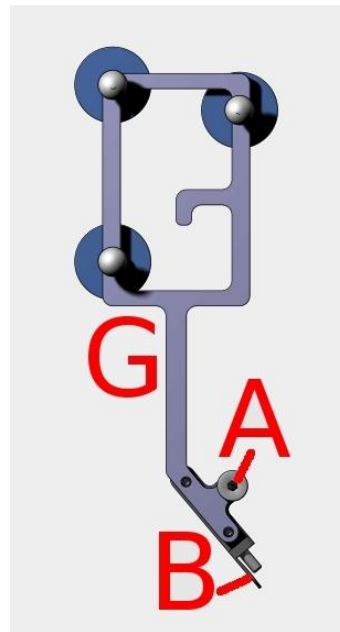
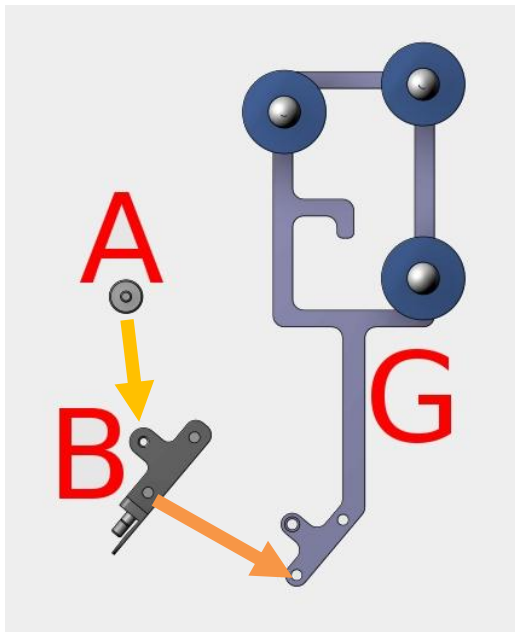




Insert the Easy-clip on the 2-spikes arm on the clamp main body, position the F-array and then lock the Easy-clip hinge using the dedicated L-shaped key.

**OPTION:** As an alternative to the Easy-clip, the pins locking clamp (ref.no. 33.22.0107 and 33.22.0108) may be used to fix the F-array to the clamp.

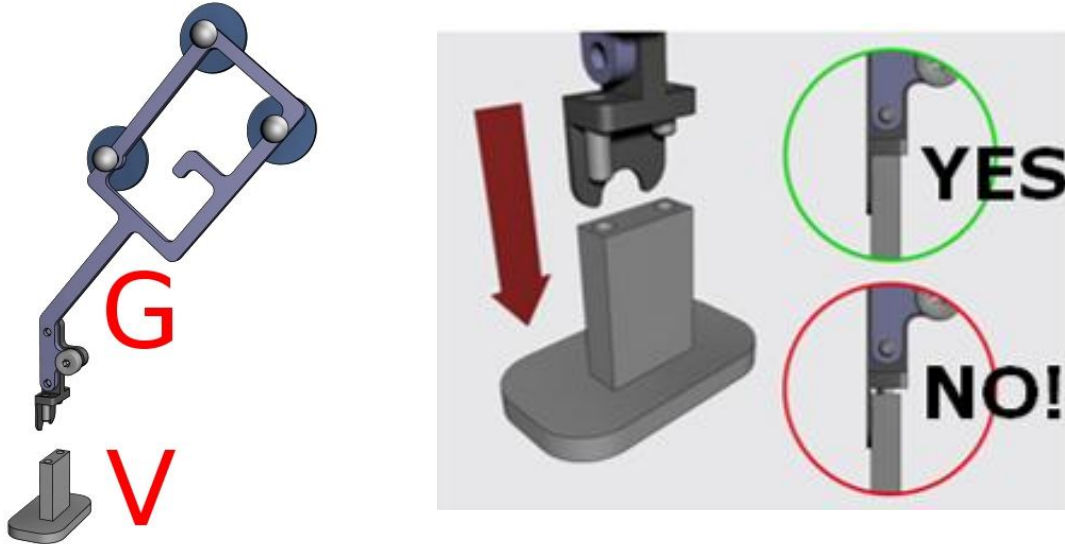
### 8.3. Assembling the G-shaped reference array



Place the adapter support (B) on the lower end of the reference array (G) stem, aligning the pins and the centering holes. Insert the screw (A) as shown in the figure on the right and tighten it with an Allen wrench.

#### 8.4. Assembling the G-shaped reference array on the verification template

To carry out the acquisition, the support pins (B in the figures above) must be inserted on the verification template (V in the figure on the side).



**When assembling the G-shaped array on the template and on the other specific tools, make sure that the array is fully seated. An incomplete insertion will lead to loss of accuracy and false information.**

### 9. ACQUISITIONS

The acquisitions are extremely important for the proper functioning of the navigation process. The quality of the information provided by the MEDACTA navigation system to the surgeon is in fact strictly related to the accuracy of the acquisitions performed using the pointer or markers fixed to bones and instruments.



**At the beginning of each acquisition the tip of the pointer (P-shaped reference array) must already be in contact with the bone surface and must absolutely not be lifted until the end of the acquisition.**

**If the user suspects that the pointer was not held in contact with the bone surface during the acquisition, repeat the procedure to avoid providing the navigator with unreliable information.**

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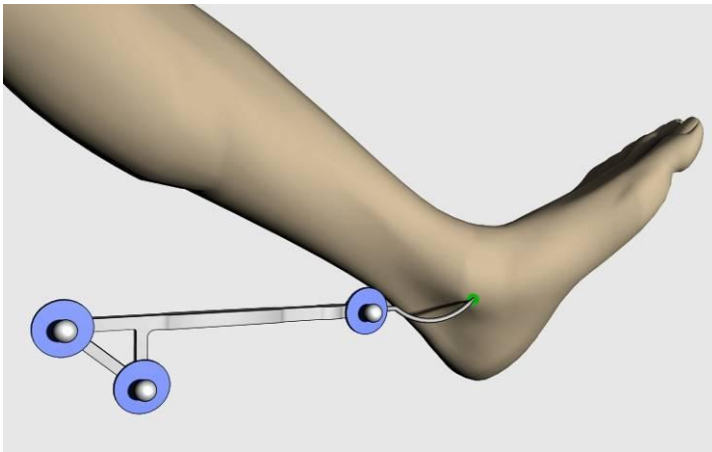
**Make sure that the cameras are perfectly still during the acquisitions. Vibrations and small movements may compromise the accuracy of the results. Between one acquisition and the next, the camera can however be repositioned according to the needs without compromising system accuracy and reliability in any way.**

---

### **9.1. USAGE OF THE POINTER**

The pointer adopted with iMNS™ can be used in three different ways, according to the kind of data being registered:

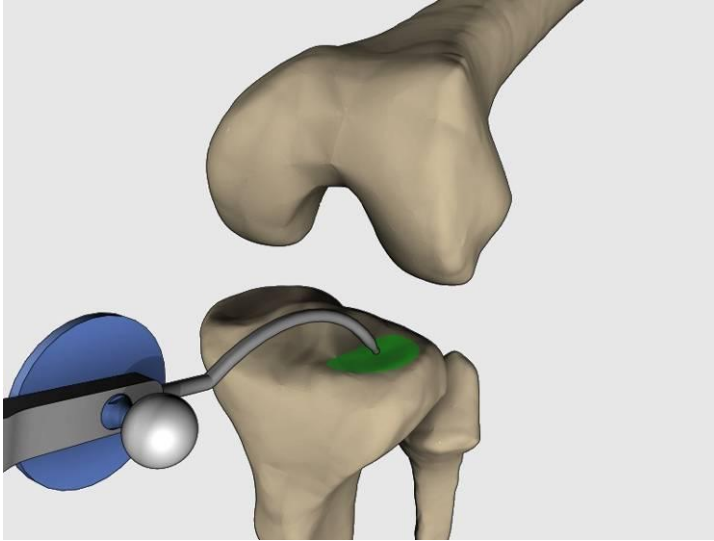
*Single point acquisition* : rest the pointer on the appropriate anatomical reference point and press F4 or right pedal.



**In order to perform an acquisition, all the involved reference arrays must be visible. A higher “BEEP” sound will inform the user when the acquisition have been done, a lower “BEEP” sound will inform the user if one of the arrays is not visible during the acquisition. In this case the acquisition will not start.**

---

*Surface acquisition* : rest the tip of the pointer on the appropriate landmark and press F4. An acoustic signal will confirm that the acquisition is ongoing. Taking care not to lift the pointer, « paint » the surface by gently moving the tip of the pointer in a spiral motion.



---

**In order to perform an acquisition, all the involved reference arrays must be visible. A higher "BUZZ" sound will inform the user when the acquisition is ongoing, a lower "BUZZ" sound will inform the user if one of the arrays is not visible during the acquisition. In this case the acquisition will not start or will be "frozen" until the needed arrays are visible.**

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## **10. PREOPERATIVE PLANNING**

### **10.1. RADIOLOGICAL PLANNING**

This is performed from the pangonogram (hip-knee-angle film), postero-anterior and lateral knee radiographs, the femoral-patellar film and from the available templates set.

The goal is to determine the angle formed by the anatomical axis and the mechanical axis of the femur to be treated, to determine the tibial slope, to trace and measure bone resections, to establish the intra-medullary guide introduction points, to assess the sizes of the femoral and tibial components, the height of the tibial insert, the thickness of patella to be resected, to study the topography of the operative site (localization of osteophytes, and mainly posterior osteophytes).

### **10.2. CLINICAL PLANNING**

The goal is to assess the range of motion of the joint and patellar centering and to assess whether deformities are established or not.

## **11. SURGICAL APPROACH**

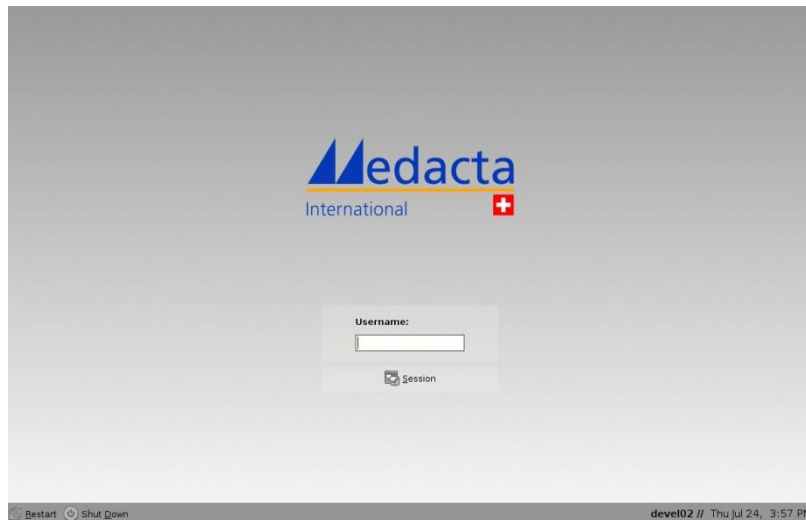
The most commonly used surgical approach is the internal para-patellar approach. The surgeon may, however, use other approaches in certain cases of revision surgery or in the case of severe valgus deformities.

Mini midvastus and Mini subvastus exposures can also be used, provided that, in the surgeon's opinion, patient characteristics are appropriate for a muscle sparing approach.

## **12. STARTING THE SOFTWARE**

Turn on the computer and wait a few seconds for the operating system to load and all the peripherals to be initialized.

The user login screen appears. Select the user "*medacta*" with password "*medacta*" (without quotations).



The applications manager screen appears. Just press *Return* to start the iMNS™ navigation software manager.



To move the cursor on GMK v4.4.0 use the *Tab* key; select the application by pressing *Return*.

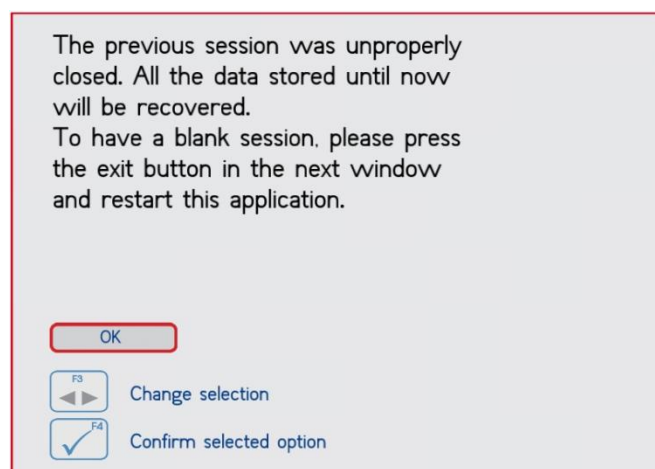
Select the desired application and press f4 to start the navigation.



## 12.1. PREVIOUS SESSION RECOVERING

The navigation process is continuously stored in the hard drive of the computer. In case of an improper termination of the navigation program (e.g. due to a power failure) it will be possible to restore the navigation process exactly as it was before the problem arose.

To do so: Select the same application that you were using when you experienced the improper termination. The following warning message will be displayed:



To restore the previous session: select "OK" and continue navigation. Recovered data will be already registered.

In case the recovery of the previous session is not needed: select "OK" and then "EXIT" to restart the software application.

## 12.2. SURGERY DATA

SETTINGS SETUP HKA PRE RESECTION ANALYSIS ANATOMICAL LANDMARKS RESECTION TRIAL IMPLANT ANALYSIS FINAL IMPLANT ANALYSIS REPORT

PROGRESSION

Surgery data: Insert surgeon's ID.

Surgery data

Surgeon dr XYZ

Surgery date mm / dd / year

ID code

Patient data

Surname

Name

☐ Male ☐ Female

Birth date mm / dd / year

☒ Metric ☐ USA

Height [m] / [cm] Weight [Kg]

Load

Exit

Here it is possible to specify the name of the surgeon and other data related to the surgery and the patient.



**Although data in this screen are optional, it is advisable to fill all the fields.**



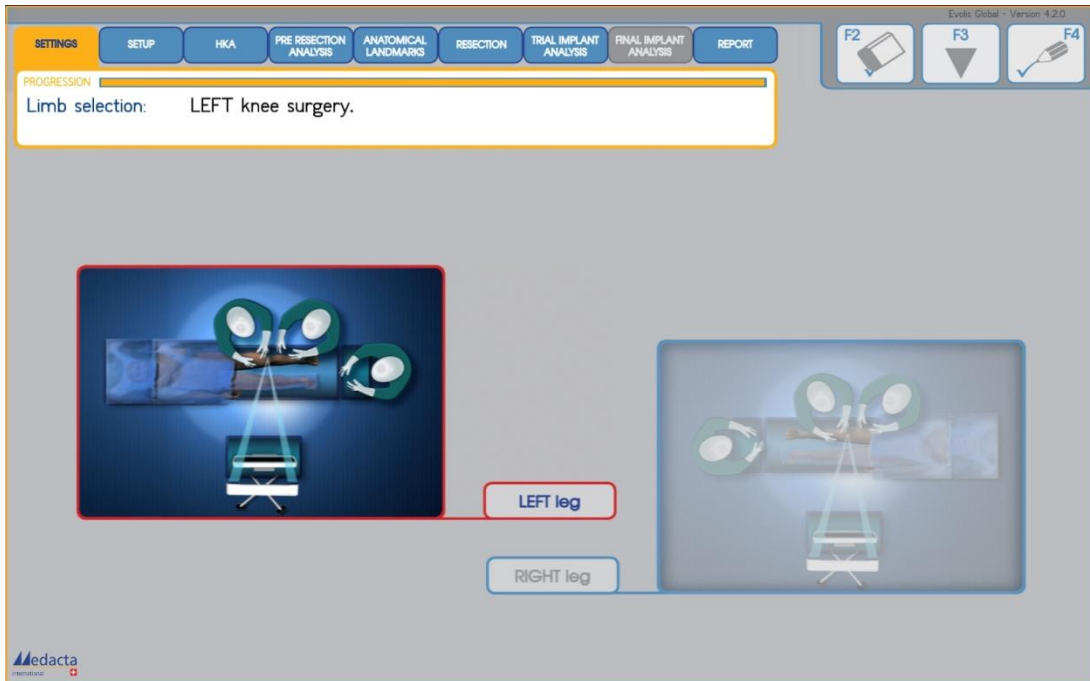
**In order to guarantee patient's privacy, the file containing the report of the surgery will record and display only the first letters of patient's name and surname.**



**After typing in the surgeon's name it is possible to load his profiles set by clicking on the "LOAD" button. This option is available only if Settings, Planning and Guides profiles have been all previously associated to the surgeon.**

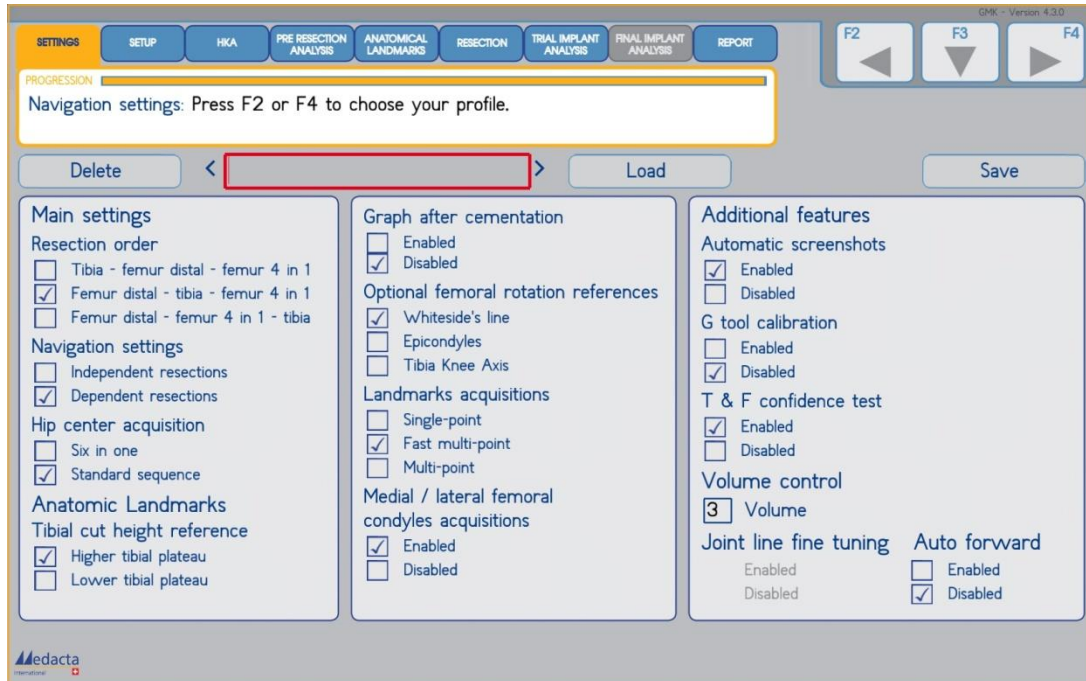
### 12.3. LIMB SELECTION

Select the limb that will undergo the surgery and place the camera according to the picture.



## 12.4. NAVIGATION SETTINGS [F6]

It is always possible, even when navigation is ongoing, to return to this step and select different options (F6 shortcuts).



### DELETE/LOAD/SAVE

These controls are used to delete, load or save an existing profile. See "MANAGING PROFILES" section.

### MAIN SETTINGS

#### - Resection order

- *Tibia – femur distal – femur 4 in 1*
- *Femur distal – tibia – femur 4 in 1*
- *Femur distal – femur 4 in 1– tibia*

#### - Navigation settings

- *Independent resections*: the navigation system will act as a measuring instrument.
- *Dependent resections*: the navigation system will suggest the resection varus/valgus angle to compensate the varus/valgus validated on distal or tibial cut.

- Hip center acquisition

- *Six in one*: one single pressure of F4
- *Standard sequence*: limb abduction, adduction and lift, each followed by F4.

ANATOMIC LANDMARKS

-Tibial cut height reference

- *Higher tibial plateau*: the less worn plateau is set as tibial cut height reference
- *Lower tibial plateau*: the most consumed plateau is set as tibial cut height reference

Select the tibial plateau that will be used to assess cut height.

- Graph after cementation

Analyze the Range Of Motion (ROM) after implantation of definitive components

-Optional femoral rotation references

The system by default shows the femoral rotation vs the posterior condyles line. Additional reference lines may be selected:

- *Whiteside's line*
- *Epicondyles*
- *Tibia knee axis (i.e. tibial mechanical axis).*

- Landmarks acquisition

- *Single-point*
- *Fast multi-point*
- *Multi-point*

Femoral landmarks can be registered by acquiring a single point or by « painting » the surface of the bone (multi-point mode).



**Single point option ("pointer-on-hand" method) and multi-points option imply a different acquisitions workflow.**

| ACQUISITION STEPS WORKFLOW        |                     |
|-----------------------------------|---------------------|
| SINGLE POINT<br>(POINTER-ON-HAND) | (FAST) MULTI-POINT  |
| pointer calibration               | pointer calibration |
| surgery start                     | surgery start       |
| camera placement                  | camera placement    |
| confidence test                   | confidence test     |
| tibial axis                       | tibial axis         |
| tibia acquisitions                | hip centre          |
| femur acquisitions                | sagittal plane      |
| hip centre                        | tibia acquisitions  |
| sagittal plane                    | femur acquisitions  |

- Medial/lateral femoral condyles acquisition

Acquisition of two reference points, one on the medial condyle and one on the lateral condyle, to assess the maximum acceptable width of the femoral component.

ADDITIONAL FEATURES

- *Automatic screenshots*

Screenshots of key steps of the navigation process will be automatically stored

- *G tool calibration*

The G reference array will be calibrated by mean of a specific tool

- *T & F confidence test*

Two references (one on the tibia and one on the femur) will be registered and used to test if "F" or "T" reference arrays moved during the surgical procedure\*.



**\*By disabling the confidence test it will not be possible to test navigation accuracy. It is strongly recommended that the confidence test is kept enabled to ensure the maximum safety.**

- *Volume control*

By pressing f2 and f4 it is possible to set the volume of the sounds emitted by the iMNS, from 0 (minimum) to 5 (maximum).

- *Joint line fine tuning (only for "tibia first" navigation)*

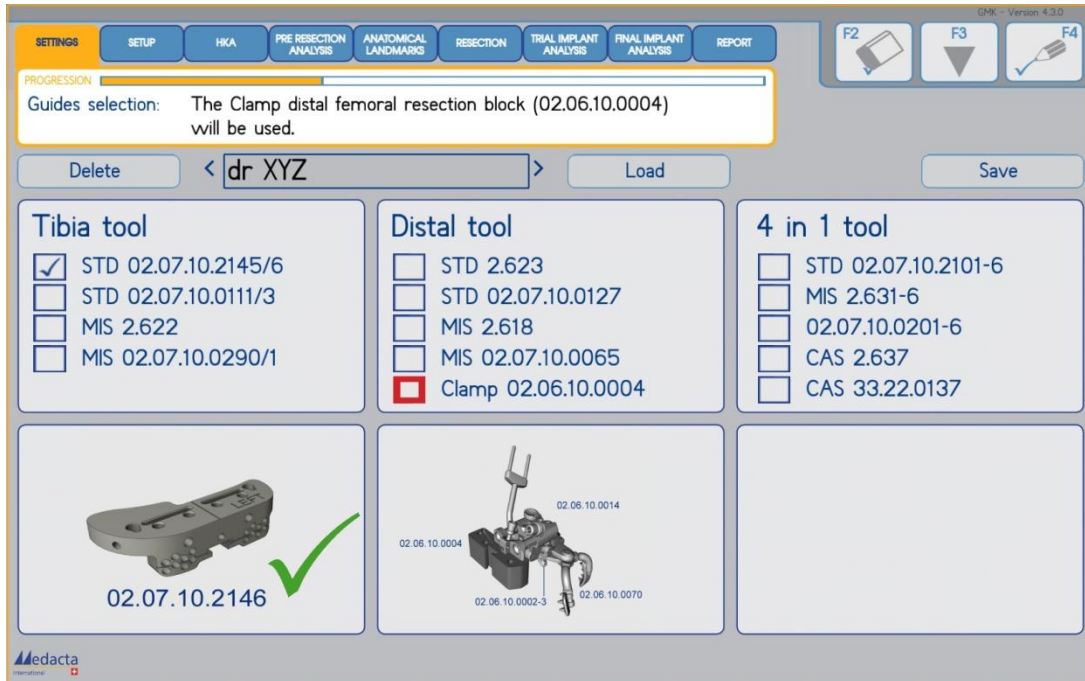
By selecting this option an additional fine tuning of the distal and posterior femoral landmarks will be performed using a spacer block.

- *Auto forward*

By enabling this option, after the last acquisition in the current screen, if any warning message is shown, the system will automatically proceed to the next screen.

## 12.5. GUIDES SELECTION

Cutting blocks and micrometric tools to navigate them can be individually selected. To visualize the selected block, move the cursor on the related box and confirm the choice by pressing f4.



The following tools can be used to navigate the bone resections:

### Tibia tools

- *STD 02.07.10.2145/6*
- *STD 02.07.10.0111/3*
- *MIS 2.622*
- *MIS 02.07.10.0290/1*

### Femur tools

#### Distal Tools

- *STD 2.623*
- *STD 02.07.10.0127*
- *MIS 2.618*

- *MIS 02.07.10.0065*
- *Clamp 02.06.10.0004*

### 4 in 1 tools

- *STD 02.07.10.2101-6*
- *MIS 2.631-6*
- *02.07.10.0201-6*  
(both for *STANDARD* and *MIS* procedures)
- *CAS 2.637*
- *CAS 33.22.0137*

### DELETE/LOAD/SAVE

These controls are used to delete, load or save an existing profile. See "MANAGING PROFILES" section.

## 12.6. SURGERY PLANNING

This screen allows to modify the cuts default parameters in order to customize the positioning of the default target reference.

Move to the corresponding box using *f3* then use *f2* (decrease) or *f4* (increase) to modify the value.

### DELETE/LOAD/SAVE

These controls are used to delete, load or save an existing profile. See "MANAGING PROFILES" section.



**Please note that the profile in the "DEFAULT CUT PARAMETERS" step is independent from the profiles set in "NAVIGATION SETTINGS" and "GUIDE SELECTION" steps.**

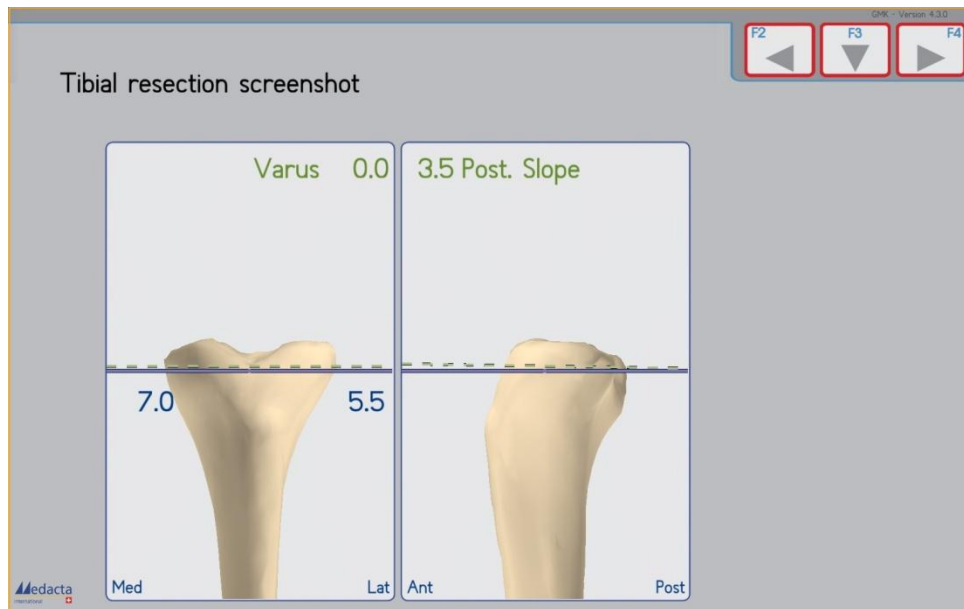
#### - Cut check

By enabling this option the system will ask to validate the cut after every bone resection (i.e. tibial, distal and anterior cuts).

If this option is kept disabled, the system will move directly to the next resection step without asking for validation of the last cut performed.

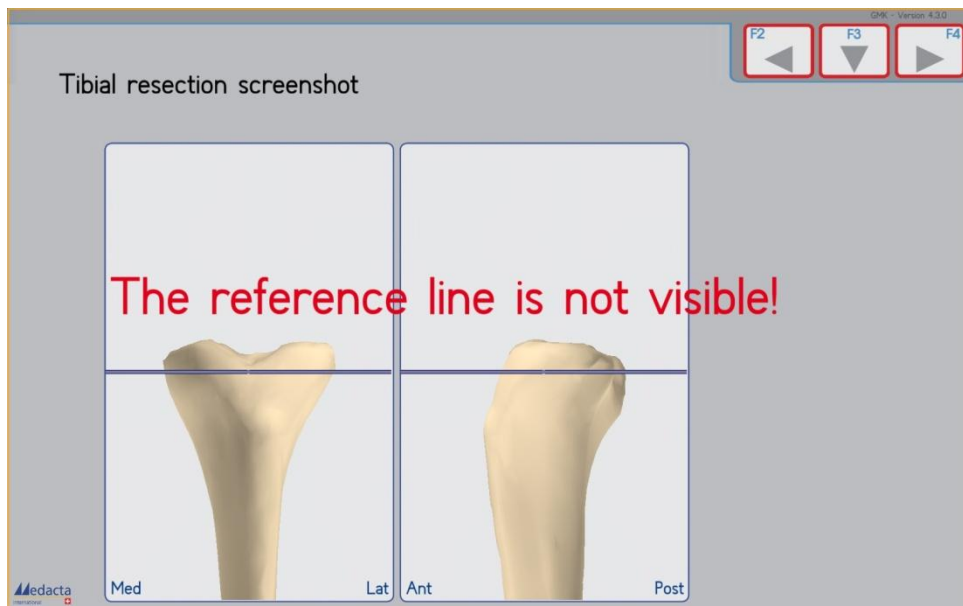
#### - Screenshot

By enabling this option, the screenshot showing the cut parameters can be frozen (*f4*) and remains available on screen after pinning the cutting guide.



**The situation shown on screen displays the resection planning not the validated cut.**

In case any rigid array is not fully visible by the camera during the screenshot acquisition (f4), the system shows the following message error:



In such a case, please go back (f2,) check on screen the rigid arrays visibility and repeat the screenshot acquisition (f4).

## 12.7. MANAGING PROFILES

Any setup in the “options” screen can be associated with a specific profile (“SAVE” function), and retrieved to be used in future surgeries.



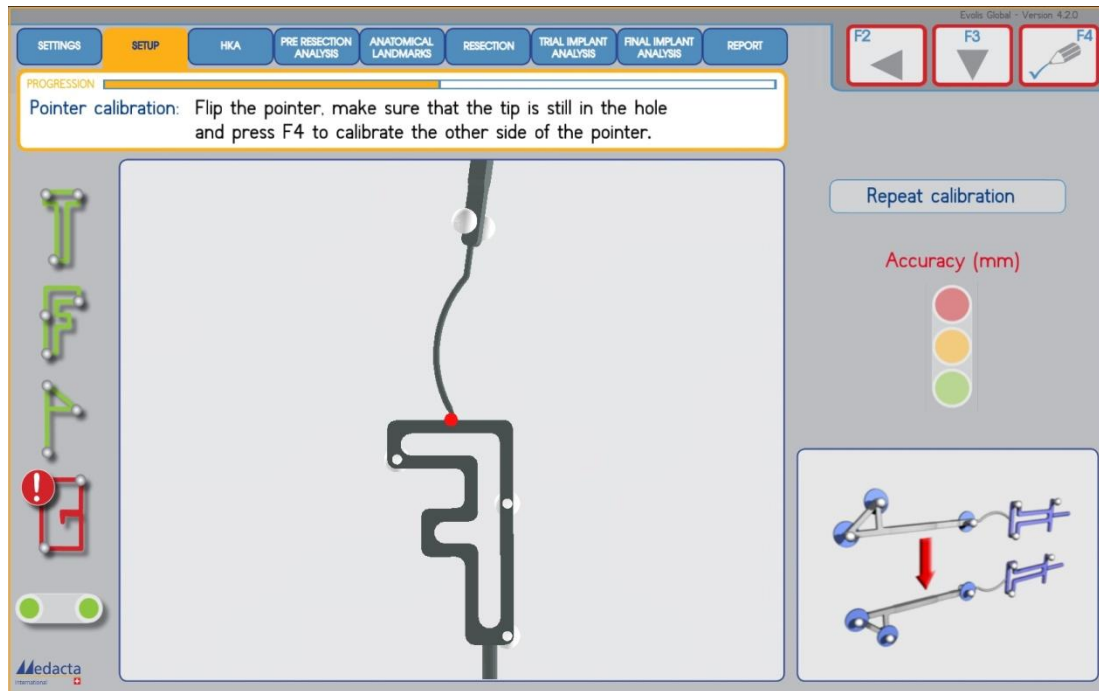
The box highlighted in the picture above displays the name of the current profile.

- A new name can be typed in the box to create a new profile.
- *Pressing f2 or f4 will scroll the list of the profiles currently stored in the iMNS.*

Once a name is displayed in the text box, a profile can be loaded, saved (this will overwrite any existing configuration associated to the selected profile) or deleted.

iMNS asks for confirmation of each of the actions above.

## 12.8. POINTER CALIBRATION



F, T or G-array can be used interchangeably.

Locate the small hole on the edge of each array. Rest the tip of the pointer in the hole and press F4. Flip the pointer 180 deg so that the other face of the tool is visible to the camera and press F4 again. Check the accuracy on both sides of the pointer by observing the traffic light symbol on screen. If the accuracy is not acceptable (yellow or red) please repeat the acquisition.



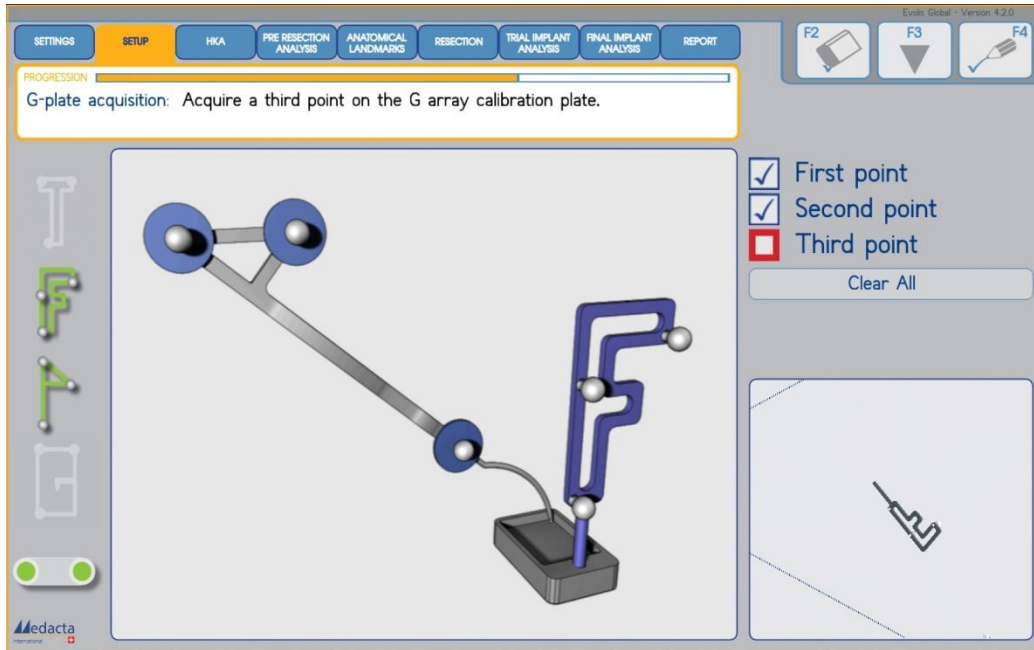
**Pointer calibration can be done by an assistant during patient preparation.**

**When acquiring, the pointer should be held perpendicular to the hole and parallel to the camera.**

## 12.9. G-TOOL CALIBRATION - Option

The G-tool (G-array) calibration ensures the maximum accuracy in cutting blocks navigation and validation of the resection planes.

G calibration is a two-stage process:



### 1) Identification of the calibration plane:

Secure the F-array on the calibration block and orient it as indicated in the picture on screen.

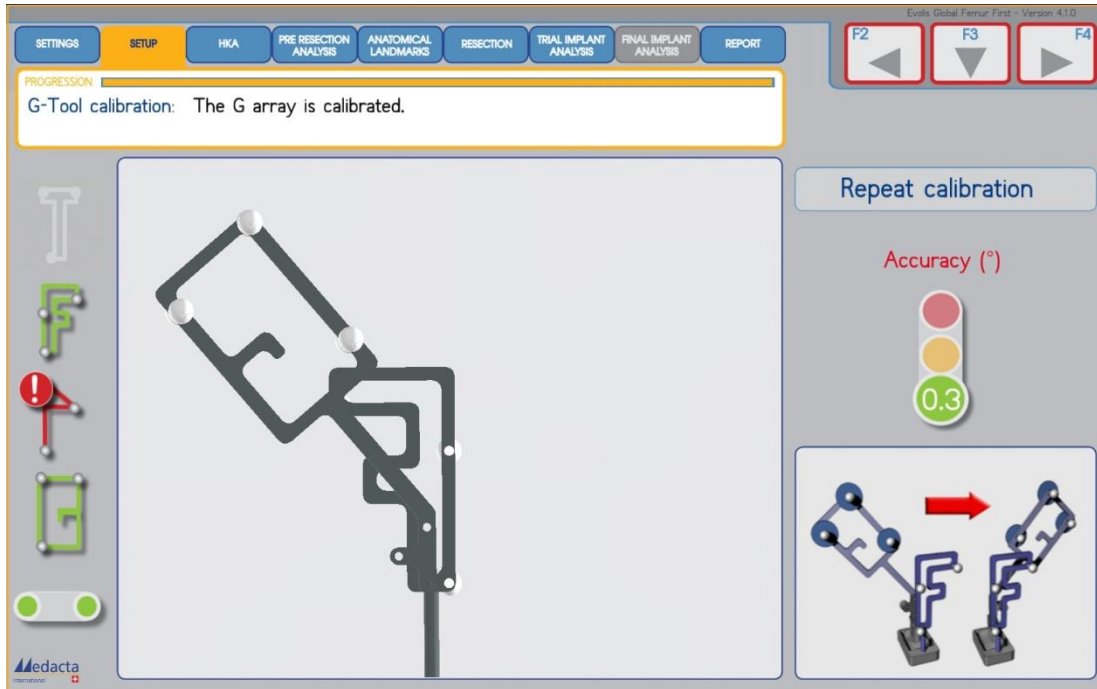


**Make sure that the screw on the calibration block is tight enough to prevent any movement of the F array**

Using the pointer, acquire three points on the calibration plane: the system will store their position relative to the F-array.



**Make sure that the pointer's tip fits perfectly into the marked reference holes.**



## 2) G-array calibration:

Assemble the verification template on the G-array.

Rest the template on the calibration plane and press F4.

Flip the G-array 180 degrees and, again, rest the template on the calibration plane to calibrate the other side of the tool.

Check the accuracy on both sides of the G-array by observing the traffic light symbol on screen. If the accuracy is not acceptable (yellow or red) please repeat the acquisition.

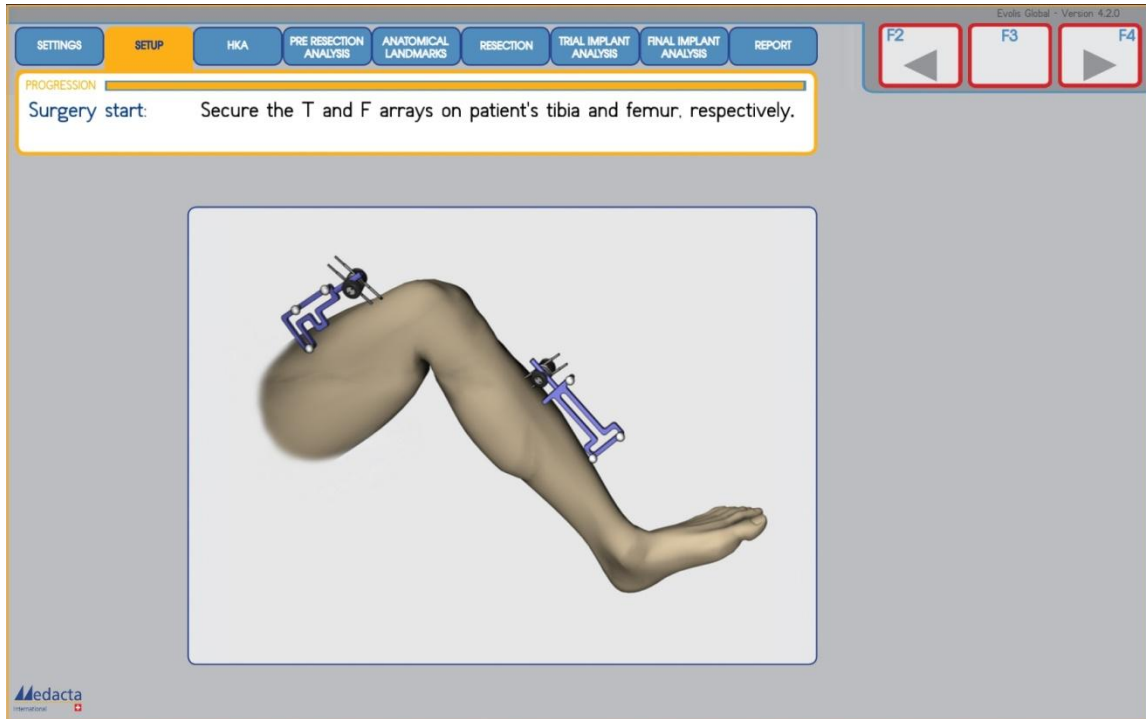


**Carefully check that all passive markers of G and F arrays are fully visible by the camera during all calibration process.**



**Firmly keep the template well in contact with the calibration plate during all acquisitions to obtain the correct accuracy.**

### 13. SURGERY START

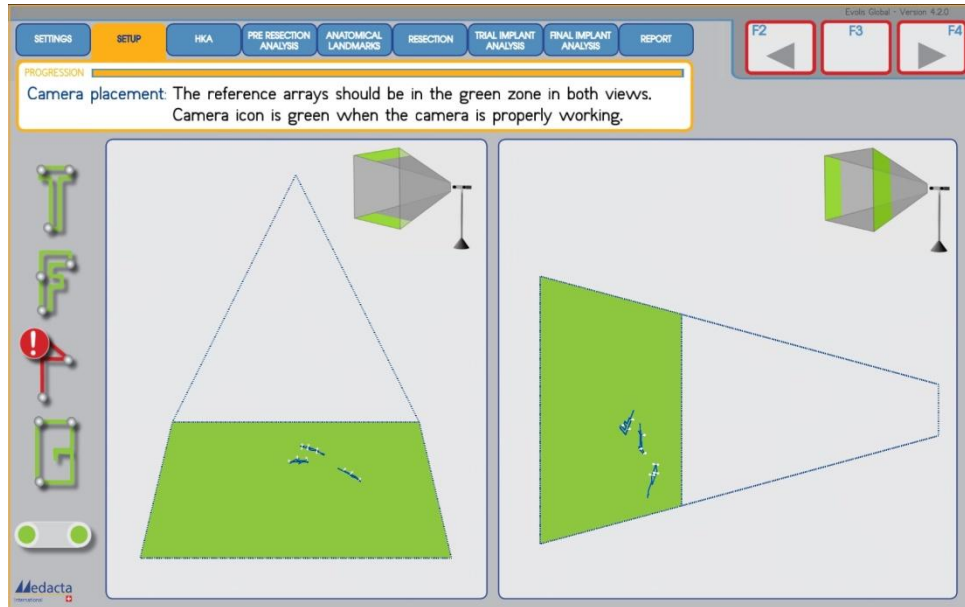


From this step on, reference arrays must be firmly attached to patient's bones.



**Different solutions may be available to fix the T- and F- arrays on the bones (see 8.2)**

### 13.1. CAMERA PLACEMENT [F7]



Move the camera so that the reference arrays are in the field of view of the camera (green region on screen).

The camera has an effective range of approximately 2.5 metres.



**The presence of infrared radiation emitters or reflectors in the field of view of the camera may hinder proper recognition of the reference arrays. In particular, should the system show recognition difficulties, make sure that all unused reference arrays are removed from the field of view of the camera and, if necessary, gently wipe the markers with a soft and dry cloth.**

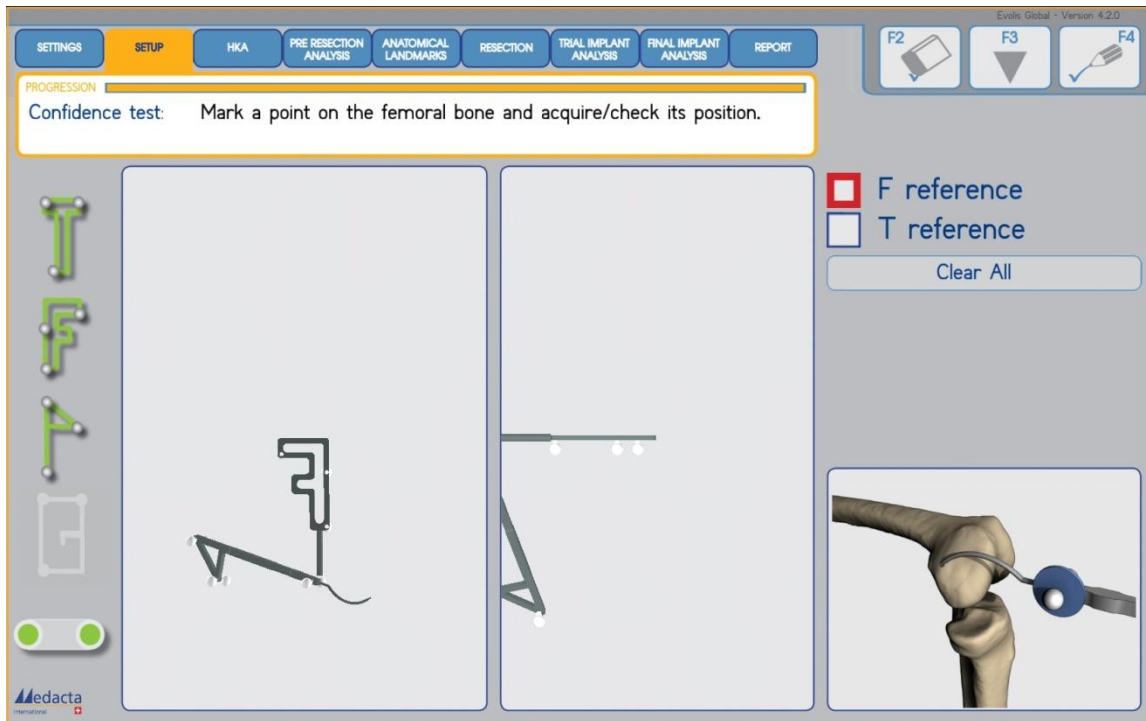


**It is suggested to check that the reference arrays that are going to be used during the surgery are recognized by the camera when placed in the field of view of the camera itself. To do so, move them in the field of view of the camera and verify that they are displayed on screen.**

**It is advisable detecting with the pointer the highest and the lowest points which could be touched during the surgery:**

- **Pointer perpendicular to the tibial plateau on a flexed knee (highest point)**
- **Pointer touching the malleoli (lowest points)**

### 13.2. CONFIDENCE TEST [F8] –Option



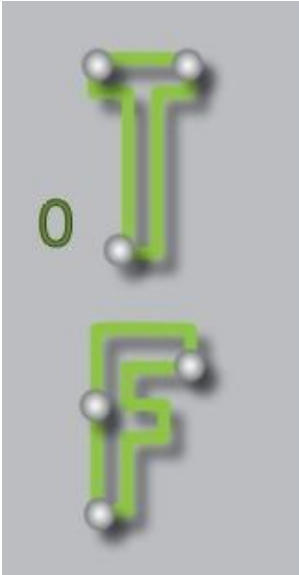
These acquisitions are extremely recommended to ensure the maximum safety.

Two points will be acquired, one on the femoral bone and one on the tibial bone. iMNS™ will store their position relative to the corresponding reference array.



**The selected points must not be resected or altered during the surgical procedure.**

### 13.2.1. TESTING CONFIDENCE



Once the two points have been acquired it will be possible to test, *during whatever stage of navigation*, if the reference arrays moved. To do so, simply rest the tip of the pointer on the corresponding reference point. A number will be displayed next to the array icon. If it is greater than 1, this means that the array has moved.

**WARNING :**

**If F or T moved, data from the navigation system are no longer reliable**



**If the test confirms that F or T have moved, one of the following actions is compulsory:**

- **Firmly secure the array and repeat the acquisitions performed so far to reinitialize the navigation process**
- **Abort navigation**



**Mark the points used as reference with an electrosurgical knife or by drilling a small hole: in case of need, it will be easier to locate them.**

**The test can be performed also on an array that is not currently in use (grayed array icon).**

**The test will not display numbers greater than 20. If, doing the test, no error is displayed this means that the amplitude of motion of the reference array is absolutely unacceptable.**

## 14. ANATOMICAL LANDMARKS ACQUISITIONS

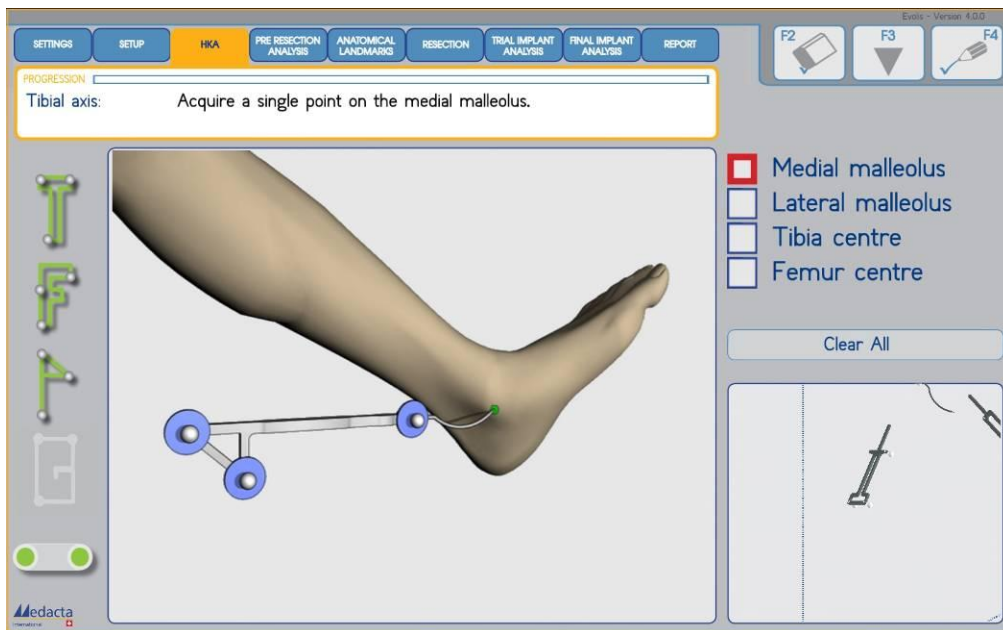
**NOTICE:** The screens workflow described in this manual follows the single point (*pointer-on-hand*) mode.

### 14.1. TIBIAL MECHANICAL AXIS

Touch with the pointer :

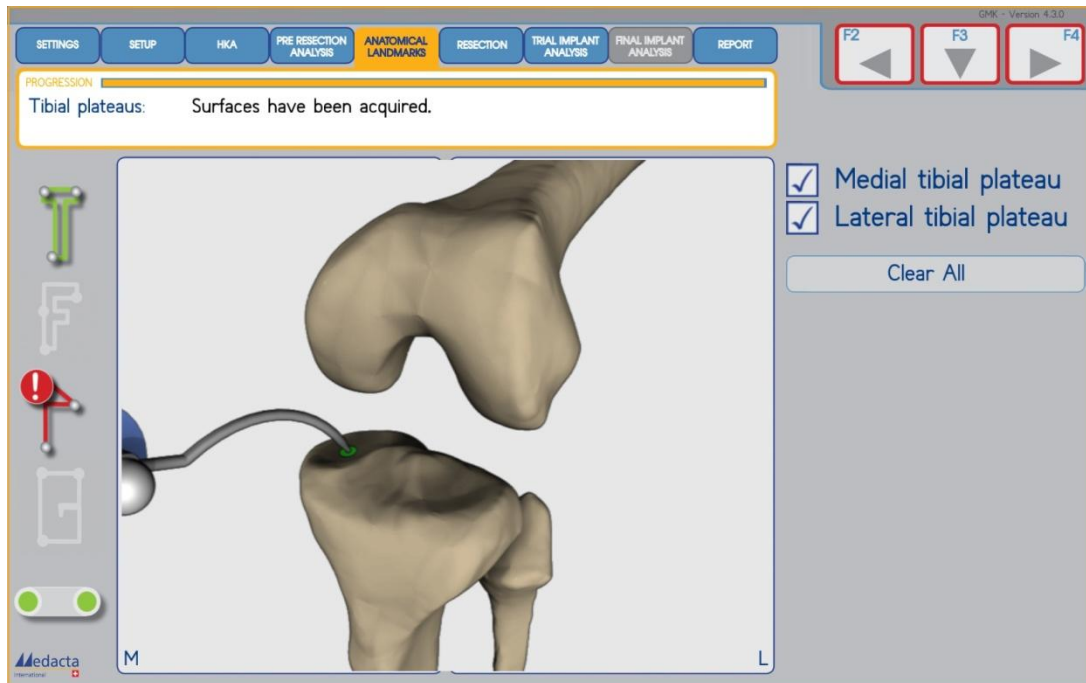
Medial/Lateral malleoli → Ankle center definition

Tibia center/Femur center → Knee center definition



The navigation system will use the malleolar references to calculate the distal extremity of the tibial mechanical axis and the tibia and femur centers to define a “virtual hinge” in the center of the knee.

## 14.2. TIBIAL SURFACES ACQUISITION

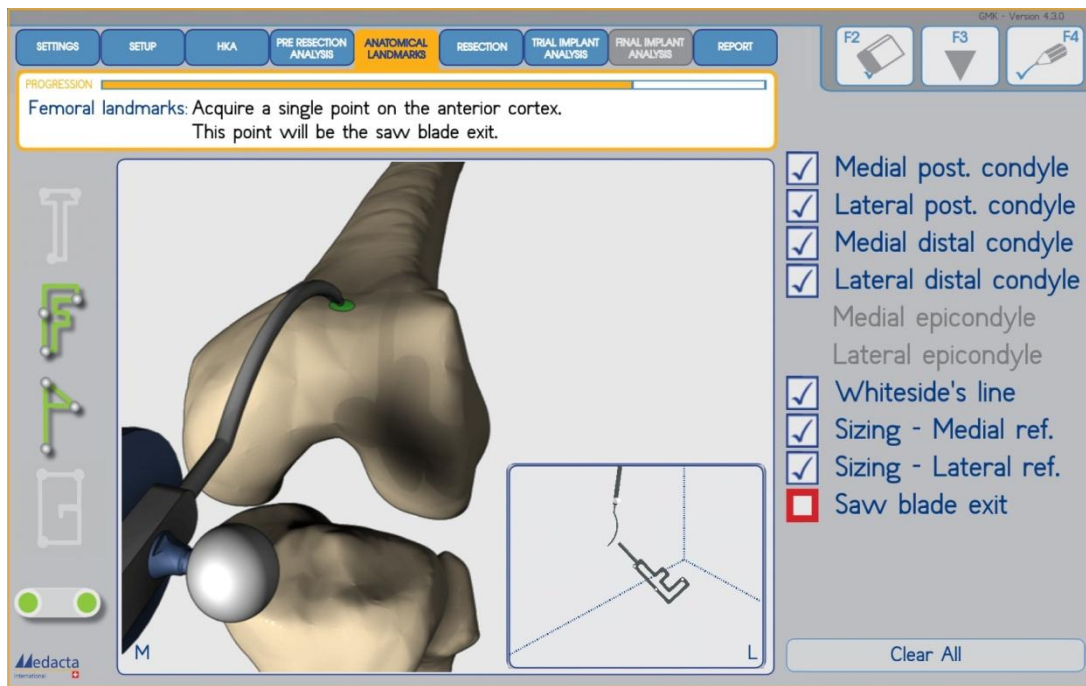


Registration of the tibial plateaus allows the system to assess tibial resection level (single point or surface acquisition).



**The graphical representation can highlight any possible lifting of the pointer that occurred during acquisition. In this case, it is in fact possible to see a red segment coming out of the profile in the graphical representation on the left of the image. Should this be the case (and in any case if the surgeon doubts of having lifted the pointer from the articular surface) the acquisition must be repeated.**

### 14.3. FEMORAL LANDMARKS ACQUISITION

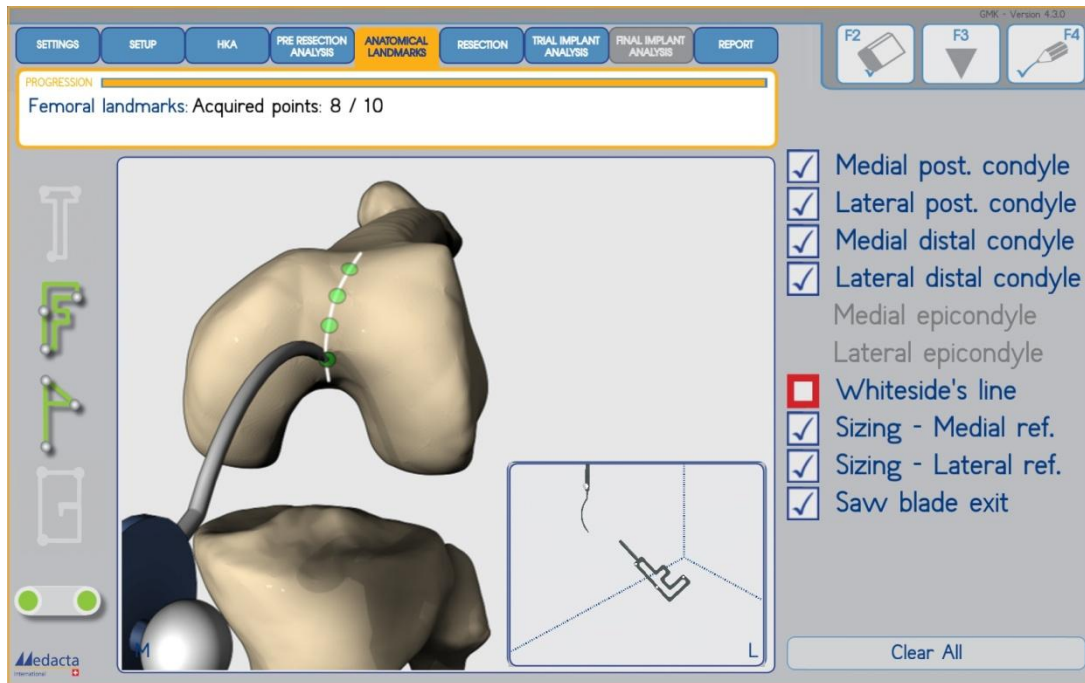


Acquisitions of references needed to navigate the external rotation and the femoral size:

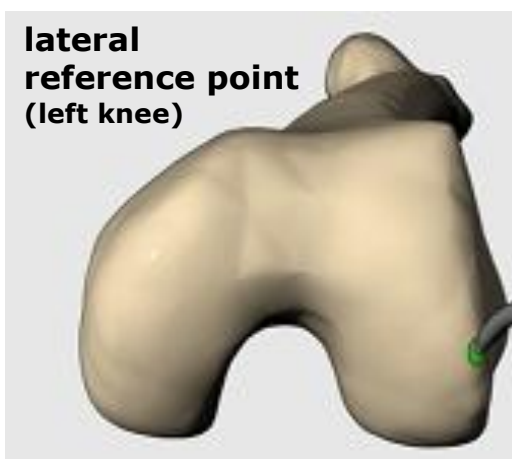
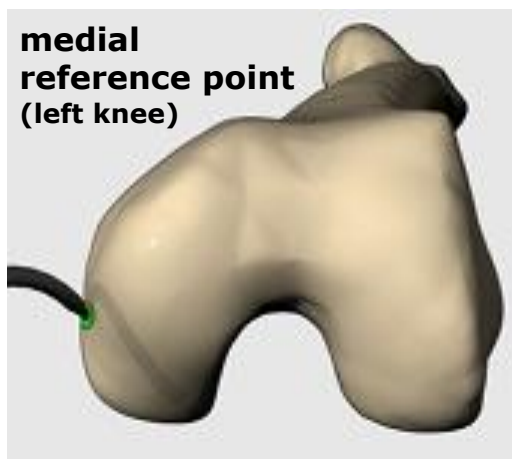
- *Medial/Lateral posterior condyle* (single point or surface acquisition): locate the most posterior points of the M/L condyles
- *Medial/Lateral distal condyle* (single point or surface acquisition): locate the most distal points of the M/L condyles
- *Medial/Lateral epicondyle* (single point acquisition only): touch with the pointer the M/L epicondyles. This acquisition is optional.
- *Whiteside's line*: acquire some single points along the Whiteside line direction until the accuracy is deemed satisfactory by the system. In case accuracy is not satisfactory a warning message appears on screen. A minimum number of 4 points and a minimum distance of 17 mm between the first and the last point are required. The Whiteside's line acquisition is optional.



**It is strongly suggested to mark the Whiteside line with an electrocautery knife to facilitate its acquisition.**



- *M/L sizing* (single point acquisition only): touch with the pointer the medial and lateral reference points that will be used to define the limits of the M/L size of the prosthesis. This acquisition is optional.



- *Saw blade exit:* locate the region of the anterior femoral cortex where you wish the blade to exit from the bone. This acquisition may be multi-point or single point, depending on the selected option (see 12.5).



---

**This acquisition affects femoral size estimation and the position of the anterior femoral cut.**

---



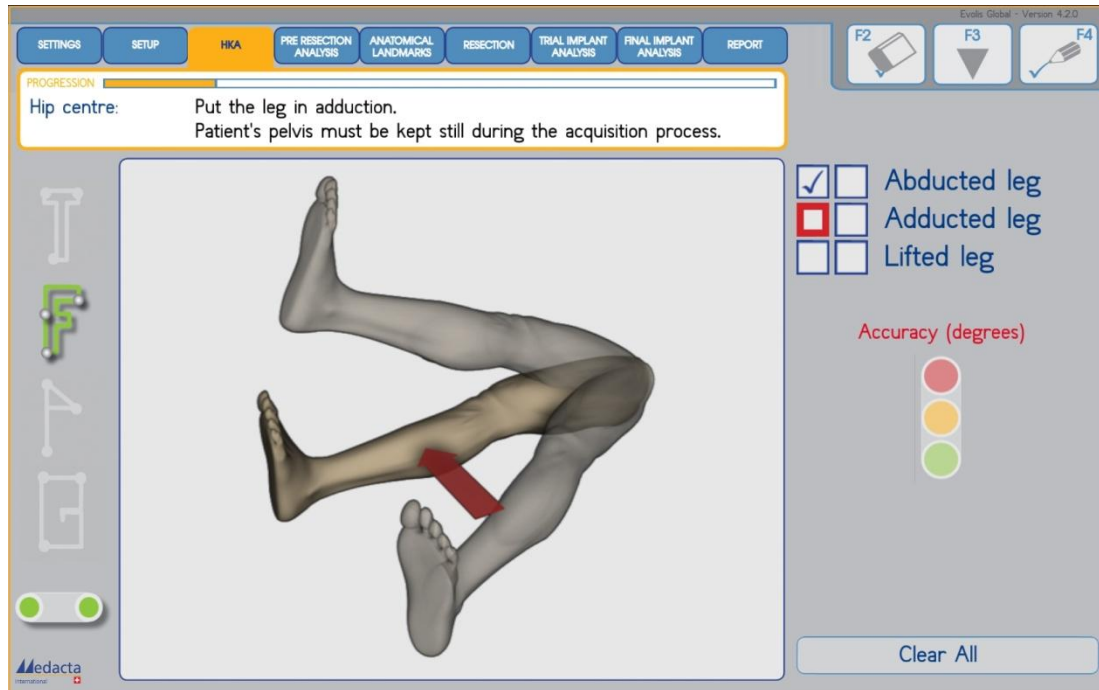
---

**Should the data presented by iMNS™ be contradictory or considered unreliable, it is recommended to repeat the corresponding acquisitions.**

---

## 14.4. HIP CENTER ACQUISITION

### 14.4.1. STANDARD SEQUENCE



A sequential abduction, adduction and lift of patient's leg is required . This maneuver has to be done twice in order to allow the navigation system to calculate acquisition accuracy (displayed in the "traffic light" on the right).

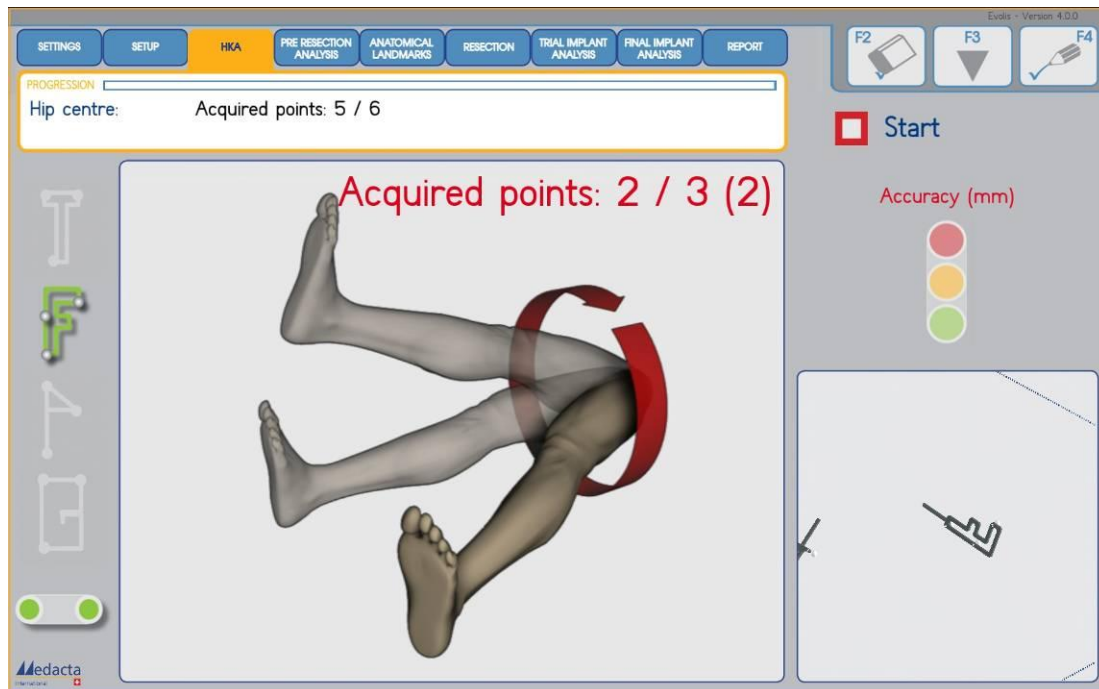


**In order to assure the accuracy of identification of the hip center, it is essential that the femur is able to make movements, even if modest, with respect to the pelvis. If these movements cannot be made, it is impossible to identify the desired point, thus precluding an accurate navigation. In such a circumstance, please abort navigation and continue with the traditional instrumentation.**



**Patient's pelvis must be kept still during the hip center acquisition**

### 14.4.2. SIX IN ONE - Option



Put patient's leg in abduction and press F4. Gently execute the following maneuver: adduction – lift – abduction – adduction - lift. An acoustic signal informs the user of the completion of each phase. Check measurement « accuracy » and repeat the acquisition in case accuracy is not acceptable.

**TIP: During acquisition keep the F array parallel to the camera.**

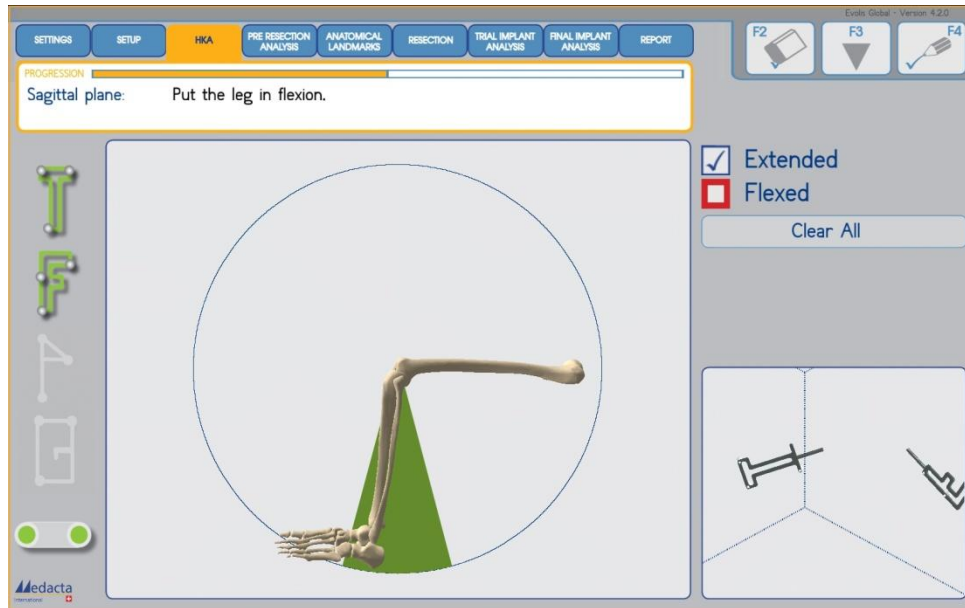


**In order to assure the accuracy of identification of the hip center, it is essential that the femur is able to make movements, even if modest, with respect to the pelvis. If these movements cannot be made, it is impossible to identify the desired point, thus precluding an accurate navigation. In such a circumstance, please abort navigation and continue with the traditional instrumentation.**



**Patient's pelvis must be kept still during the hip center acquisition**

## 14.5. SAGITTAL PLANE ACQUISITION

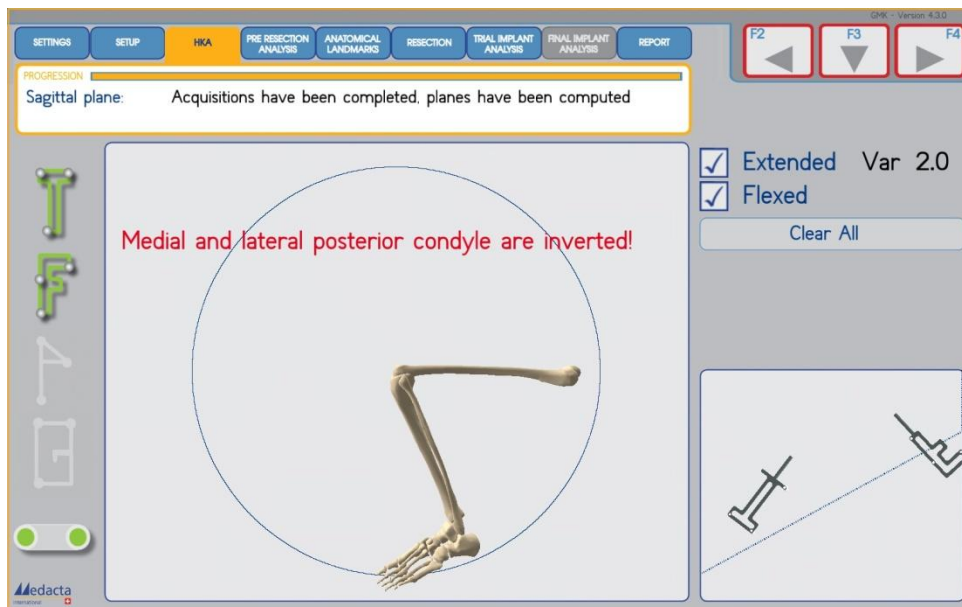


Put patient's limb in extension first and then in flexion. Acquire each stage. Once the sagittal plane is calculated, the system will be able to assess varus/valgus.

### FOR SINGLE POINT OPTION ONLY:



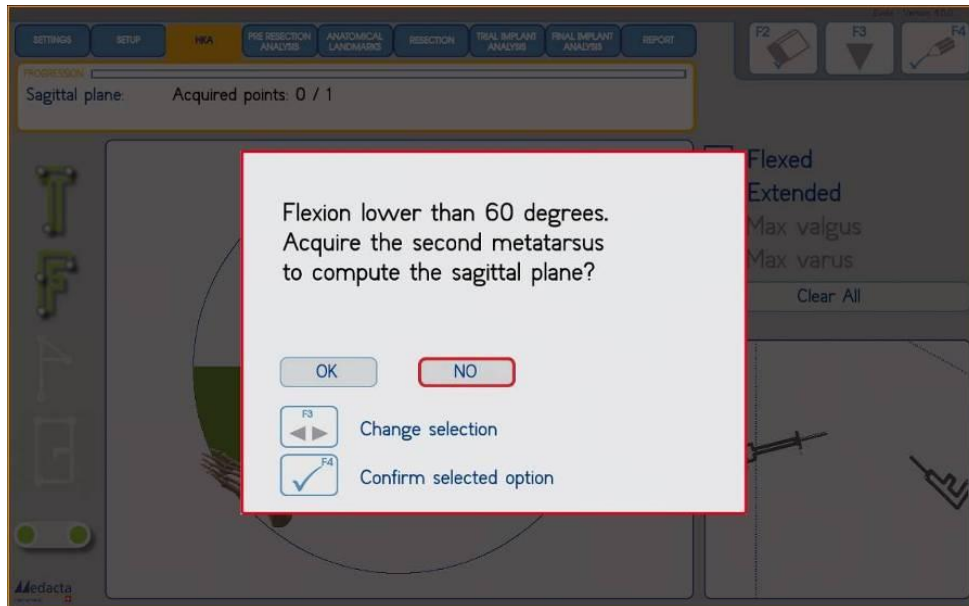
**If any medial/lateral acquisitions on the tibia or on the femur have been previously inverted, a warning is now shown on screen. In such a case, go back to the acquisition step and repeat the wrong acquisitions.**



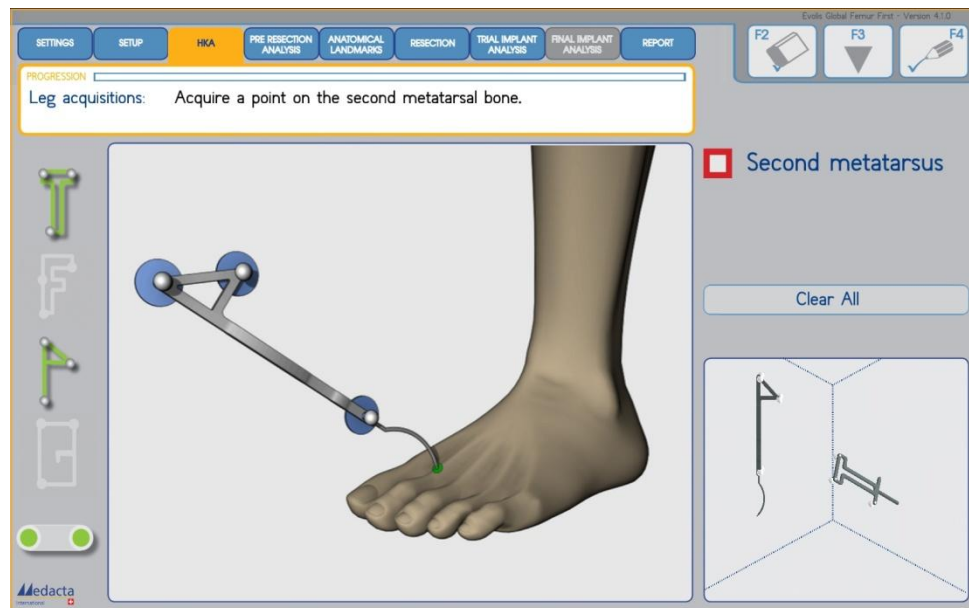


**If it is impossible to reach at least 60 degrees of flexion, the accuracy of sagittal plane acquisition is at risk of being inadequate.**

The iMNS™ system will therefore suggest to define the sagittal plane by acquiring an additional reference point on the second metatarsal bone.

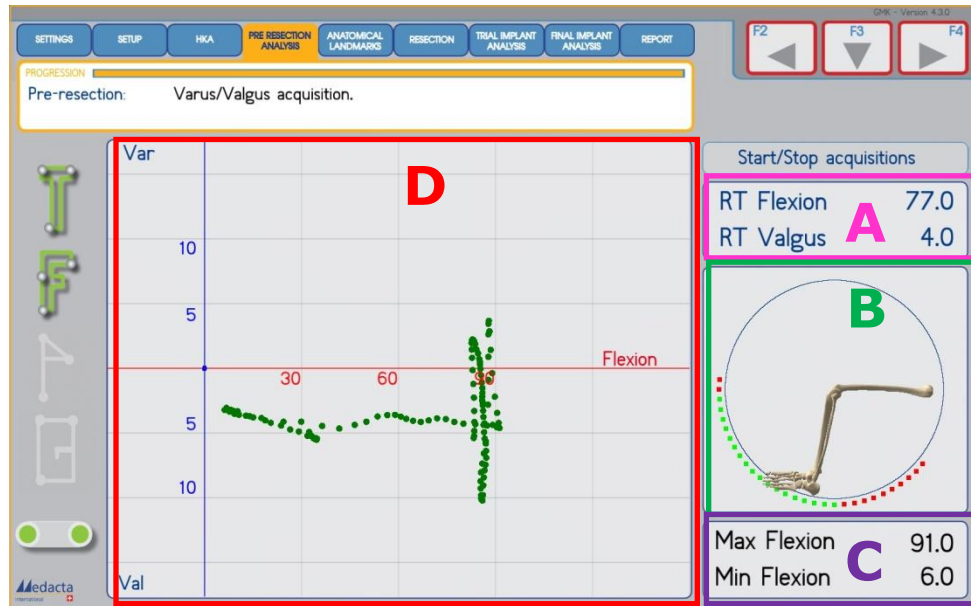


Select “OK” on the screen then move to the next screen to perform the acquisition of the second metatarsal bone landmark:



## 14.6. PRE-RESECTION ANALYSIS

This step allows performing a real-time kinematic analysis of the knee along the entire range of motion (ROM). Current varus/valgus values at different flexion angles are plotted on screen.



### A: REAL-TIME (RT) DATA

Real time flexion and varus/valgus are displayed and constantly updated.

### B: ROM INDICATOR

The range of motion is segmented in sectors of 5 degrees, indicated by the colored squares. Squares are initially red and become green once the corresponding varus/valgus sample has been recorded.

### C: MAX VALUES

Maximum and minimum flexion (i.e. maximum extension) are displayed here.

### D: PLOT AREA

Kinematics of the knee joint are plotted using green dots (real-time).

x-axis (horizontal): flexion angle. Each unit of the grid corresponds to 30 degrees

y-axis (vertical): varus (upper half) and valgus (lower half). Each unit of the grid corresponds to 5 degrees.

Press f4 to activate "START/STOP acquisitions" and begin registering data. A higher "BUZZ" sound will inform the user when the acquisition is ongoing, a lower "BUZZ" sound will inform the user if one of the arrays is not visible

during acquisition. In this case the acquisition will be stopped until all the arrays are visible again.

Once the desired data are registered press f4 again to stop registration. A snapshot will be automatically taken and the cursor will move to the navigation box.

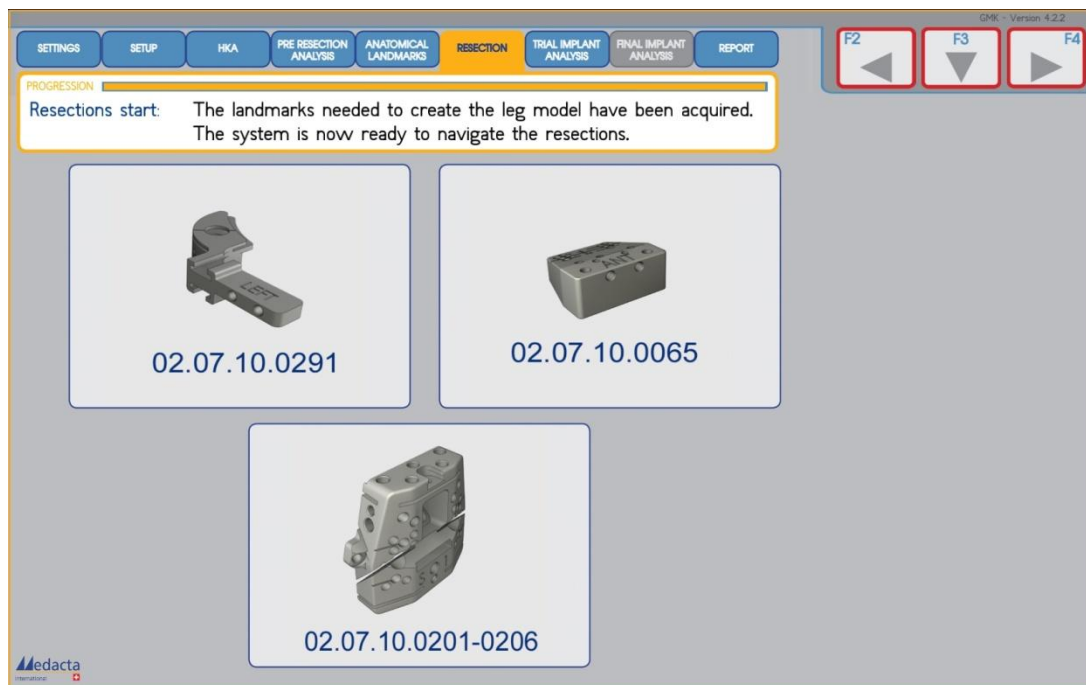
To acquire a new graph, move the cursor to "*START/STOP acquisitions*" using f3, then press f4.



**Please note that the previous graph will be deleted but any existing snapshot will be kept in memory.**

## 14.7. END OF REGISTRATION PHASE

This step informs that the registration phase has been completed and displays the instruments needed in the following steps. Depending on the technique selected in the "Navigation settings" screen, tibial or femoral instrumentation will be required first.

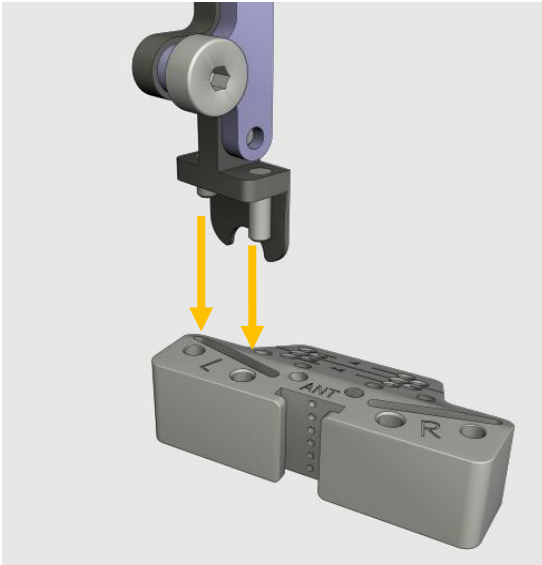


## 15. DISTAL FEMORAL RESECTION

*Option*

For distal cutting blocks ref.no. 2.623 and 02.07.10.0065 please refer to Appendix 1.

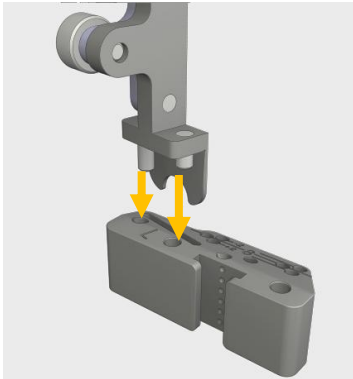
### 15.1. ASSEMBLING THE G-ARRAY ON THE DISTAL CUTTING BLOCK



#### **[STD 02.07.10.0127]**

The same block is used on a left or a right femur. Insert the G-array in the two holes marked with an "L" – left knee- or an "R" –right knee-.

MSS



#### **[MIS 2.618]**

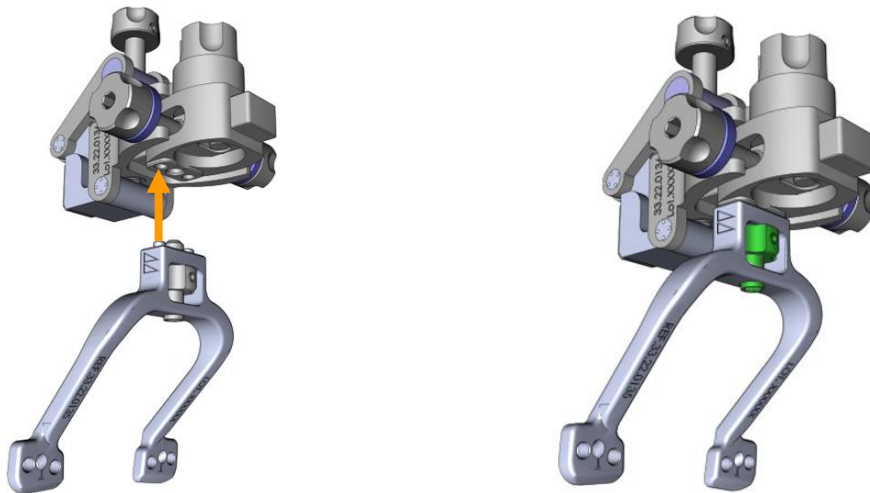
The same block is used on a left or a right femur. Select the appropriate side of the cutting block according to the knee undergoing surgery and insert the G-array in the two corresponding dedicated holes.

## 15.2. THE MEDACTA DT - MICROMETRIC POSITIONER

The DT - micrometric positioner allows the micrometric placement of the distal and tibial cutting blocks, by adjusting cut height, varus/valgus and flexion (or slope) under computer assistance.

The DT - micrometric positioner can be fixed on the femur by mean of the DT - micrometric support.

### 15.2.1. ASSEMBLING THE DT - MICROMETRIC POSITIONER ON THE DT - MICROMETRIC SUPPORT



To navigate the distal resection by mean of the micrometric system the following components must be assembled:

- DT - Micrometric Positioner [Ref.no. 33.22.0136]
- DT - Micrometric Support [Ref.no. 33.22.0135]

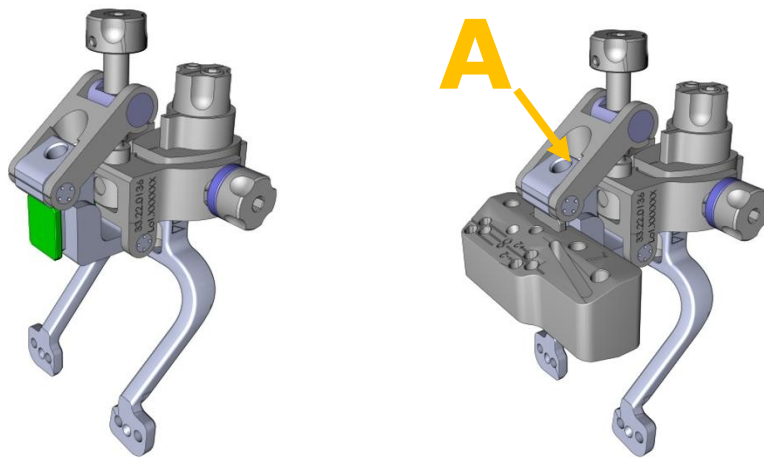
Assemble the DT - Micrometric Support on the 3-hole socket on the micrometric positioner, as shown in the picture above on the left. Fix the assembly by turning the knob highlighted in green in the picture above on the right. Finally secure the connection by mean of a screwdriver.

### 15.2.2. ASSEMBLING THE DISTAL RESECTION BLOCK ON THE DT - MICROMETRIC POSITIONER

---

**TIP:** Before fixing the micrometric positioner on distal block, set the regulation screws in the middle position in order to have the possibility to fine tune the block position in both directions.

---



Locate the flat coupling surface on the micrometric positioner (highlighted in green in figure above, left) and slide the selected distal resection block on it.  
-Figure above, right displays the assembling of a left MIS distal resection block.-

Once the block is fully inserted in position, secure the assembly by turning the locking screw (A in the picture above, right).

### 15.2.3. POSITIONING THE ASSEMBLY DISTAL RESECTION BLOCK + DT MICROMETRIC POSITIONER ON THE FEMUR

Assemble the G-shaped array on the selected cutting block (see 15.1) and make sure that the latter is firmly attached to the micrometric system.

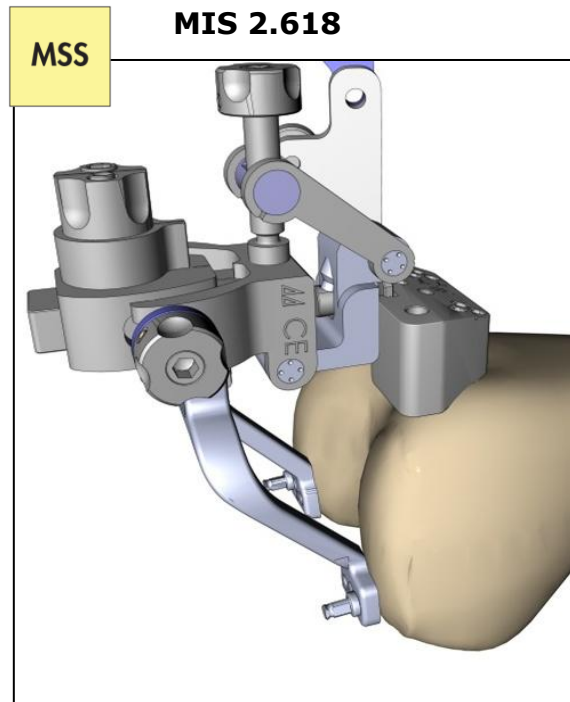
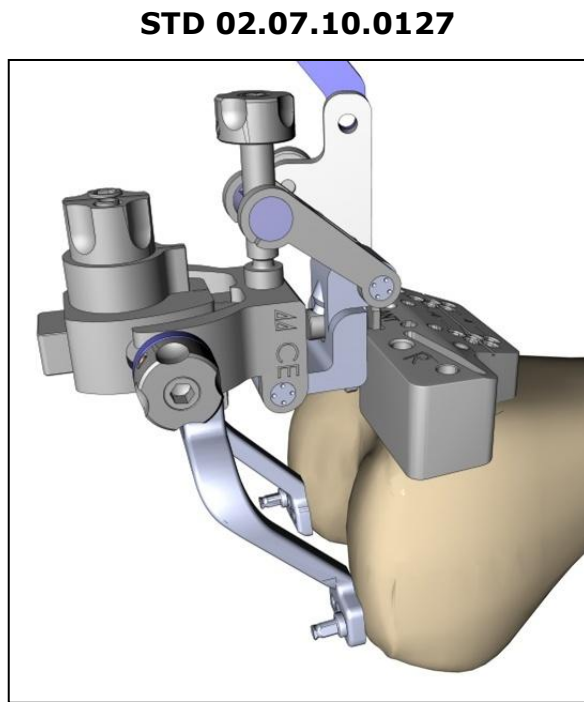
Before positioning the assembly on femur, set the parameters (see 15.2.4) close to the target position and finally fix the DT - micrometric support to the distal condyles by inserting two/four 3.2 mm pins in the dedicated holes.

The following pin holes can be used:

Green: femoral pins



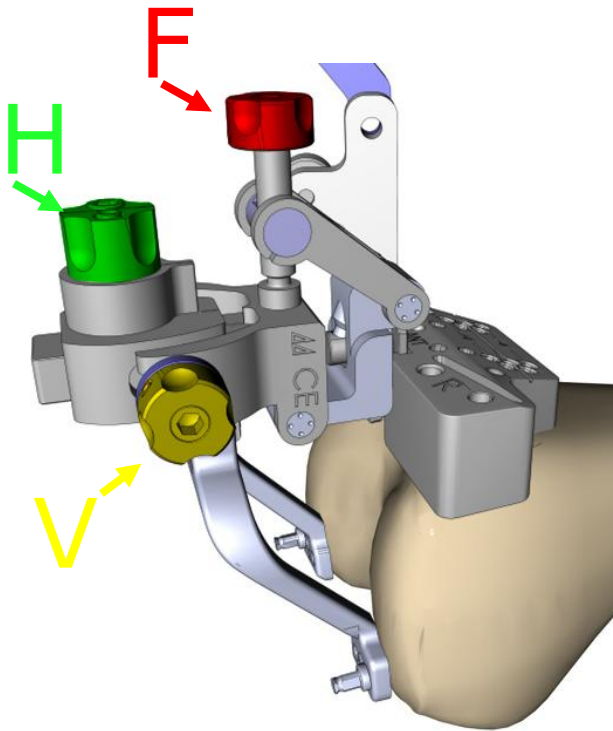
The following pictures illustrate the positioning on a left knee.



#### 15.2.4. MICROMETRIC ADJUSTMENTS USING THE DT - MICROMETRIC POSITIONER

The DT - micrometric positioner allows micrometric fine tuning of the position of the block.

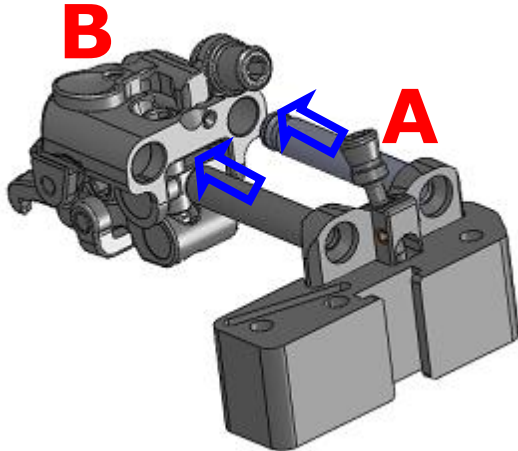
Adjustments are performed by turning specific knobs, as indicated in the figure below.



F: Flexion adjustment  
H: Cut height adjustment  
V: Varus/Valgus adjustment

### **15.3. THE MEDACTA FEMORAL CLAMP**

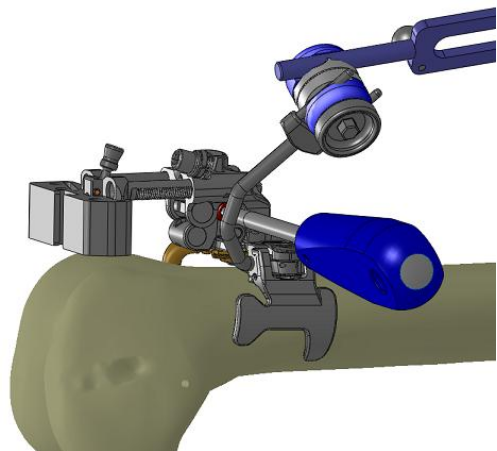
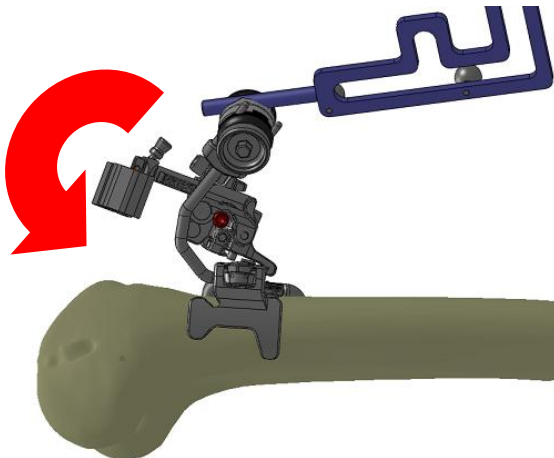
#### **15.3.1. ASSEMBLING THE DISTAL RESECTION BLOCK ON THE DT - MICROMETRIC POSITIONER**



Slide the distal cutting block on its support and fix the connection screwing the screw A. Push the button B and insert this support on the two holes located on the micrometrical positioner (blue arrows). Release the button A to fix the position of the distal cutting guide.

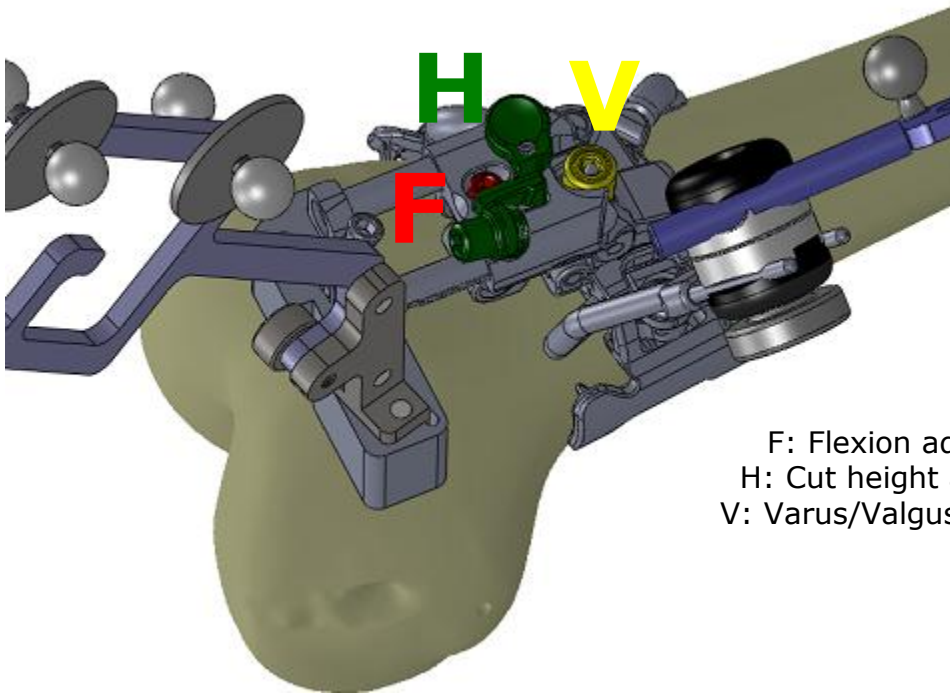
#### **15.3.2. POSITIONING THE ASSEMBLY DISTAL RESECTION BLOCK + MICROMETRIC POSITIONER ON THE FEMORAL CLAMP**

Engage the micrometrical positioner and rotate it on the clamp (pic. below, left). Turn the screw to fix the connection as shown in the picture below, right.



### 15.3.3. MICROMETRIC ADJUSTMENTS USING THE FEMORAL CLAMP MICROMETRIC POSITIONER

The distal cutting block position can be regulated by using dedicated knobs under computer guidance.



F: Flexion adjustment  
H: Cut height adjustment  
V: Varus/Valgus adjustment

Flexion: fine tuning can be obtained by turning the screw using a screwdriver.

Varus/valgus: pushed down the button by using a screwdriver and manually rotate the cutting block. When the position is deemed satisfactory, release the pressure on the button and give an additional turn to fix the position.

Cut height:

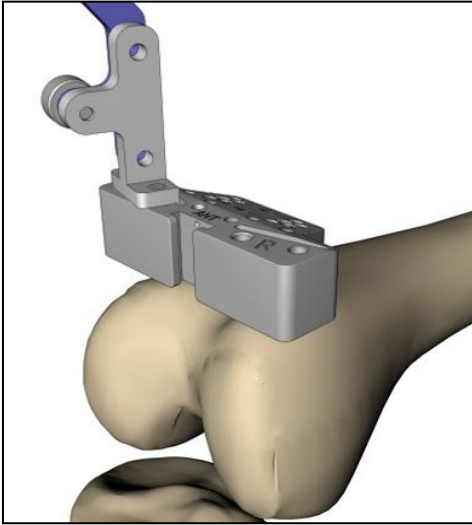
- macro tuning: push the button and slide the distal cutting block; release the button to fix the position
- fine tuning: turn the screw by using the screwdriver.

When the distal cutting guide position is deemed satisfactory, remove the G-array, connect the saw capture to the block and perform the distal cut.

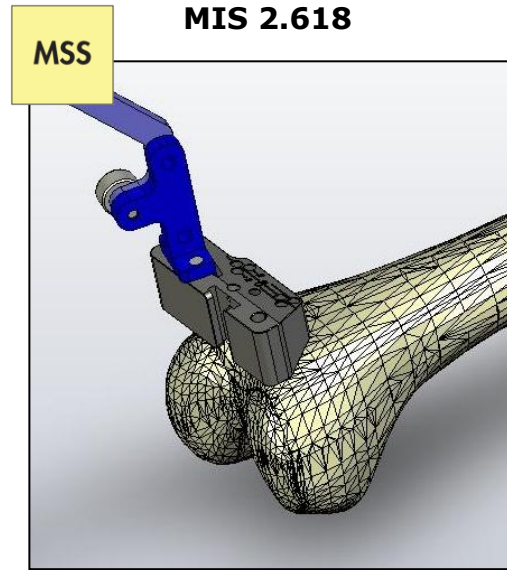
## 15.4. POSITIONING THE DISTAL CUTTING BLOCK FREEHAND

It is possible to navigate the freehand positioning of the distal cutting blocks. To do so, assemble the G-array on the block, as described in 15.1. Rest the block on the anterior condyles and, under navigation guidance, fine-tune the positioning.

**STD 02.07.10.0127**



**MIS 2.618**

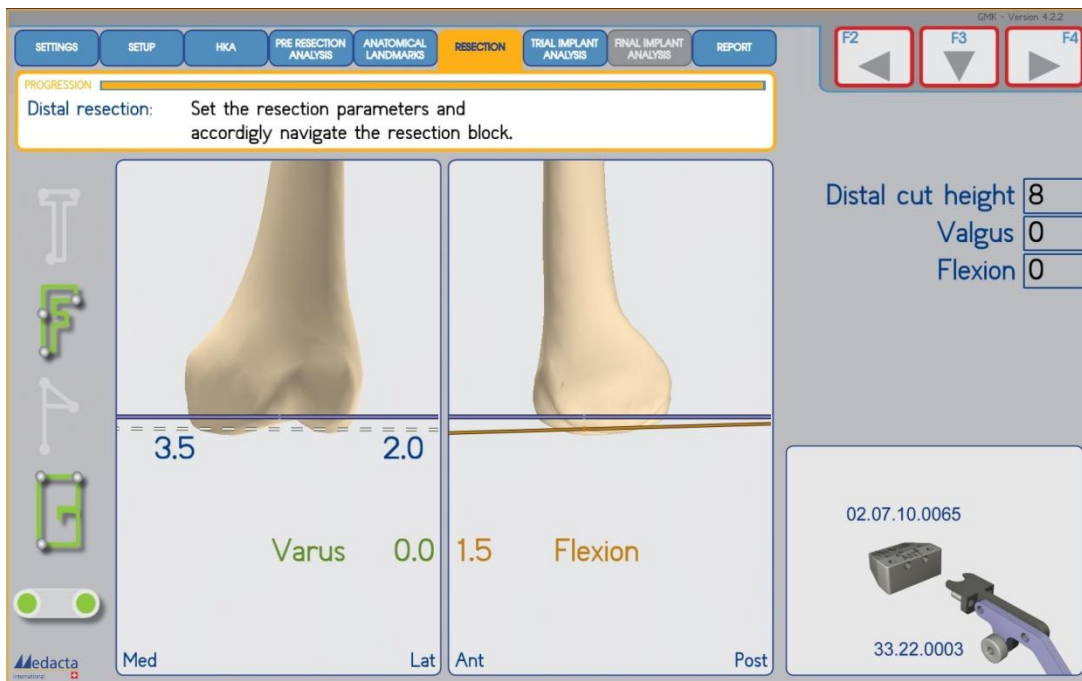


## 15.5. NAVIGATING THE DISTAL FEMORAL RESECTION



**Before proceeding with the navigation of the resection block it is advisable to perform a confidence test on T and F arrays.**

Assemble the « G » array on the distal cutting block .



Default resection parameters are displayed on the right. They can be set according to the surgeon's preferences (see "Default cut parameters"). This operation will move the bone model displayed on screen so that its orientation is accordingly updated with respect to the "target" blue lines.

Real-time values show varus/valgus, flexion and cut height on both condyles obtained during navigation of the cutting block.



**The numerical value in the field HKA (Hip-Knee-Ankle axis) Varus/Valgus is calculated as:**

$$\text{Validated Tibial V/v} + \text{Planned Distal V/v.}$$

HKA Varus/Valgus equals 0 if the planned distal resection compensates the validated tibial resection.



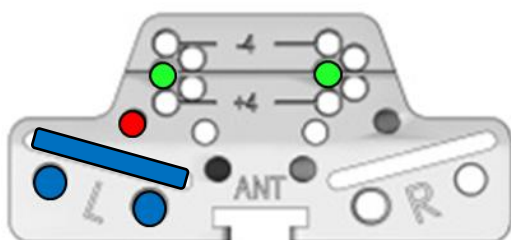
**The field HKA Varus/Valgus will not be displayed in case a femur-first procedure was selected.**



**It is advisable to always check the cut, using the conventional instruments, before resecting.**

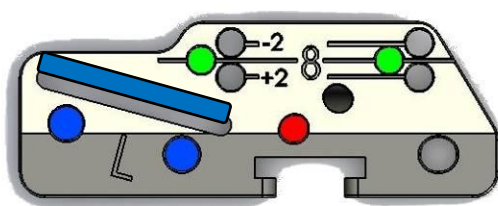
## 15.6. SECURING THE DISTAL RESECTION BLOCK

Once the positioning of the block is deemed satisfactory, it can be stabilized using parallel pins, that still allow a correction of cut height, and an oblique pin to firmly hold the block in position. The following diagrams display the layout of the pin holes. 3.2 mm diameter pins are used.



STANDARD BLOCK  
(STD 02.07.10.0127)–  
left knee

Green: parallel pins  
Red: oblique pin  
Blue: G-array



MIS BLOCK  
(MIS 2.618) – Left knee

Green: parallel pins  
Red: oblique pin  
Blue: G-array



**It is advisable to insert the pins under power control, to avoid pinning the block in malalignment. Ensure low drilling speed to reduce heat generation.**

## 15.7. DISTAL FEMORAL RESECTION

Before performing the distal resection, tools that could interfere with the saw blade must be removed.

Check the final alignment of the block and gently remove the G-array.

---



**It is suggested to double check the cut by mean of the conventional sickle finger before cutting.**

---

Insert the saw capture on the block to ensure a more accurate resection and, using a 1.27 mm blade, accurately resect the bone, taking care protecting soft tissue from injury.

---



**To help relaxing the quadriceps muscle and reduce tension on the cutting block, it is advisable to perform the cut with the leg approximately 50-60 degrees flexed.**

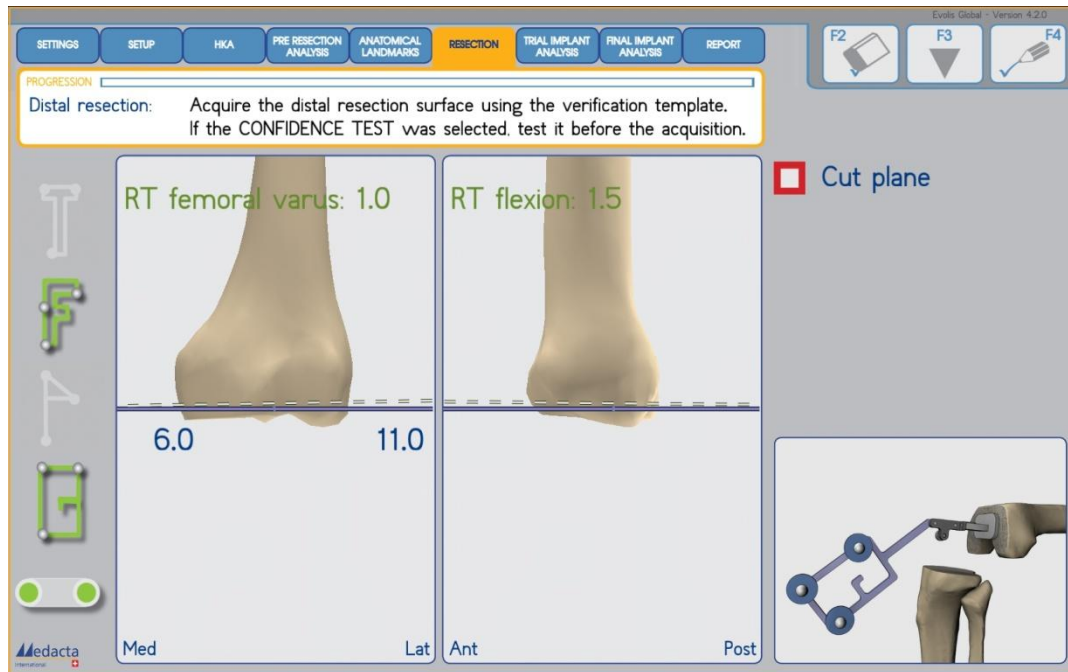
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**In case the CAS 4in1 positioner will be used to align the 4in1 cutting block, it is recommended to keep the distal cutting block in position once resected.**

---

## 15.8. DISTAL FEMORAL RESECTION VALIDATION [Option]



**Before validating the resection plane it is advisable to perform a confidence test on T and F arrays.**

Assemble the "G" array on the verification template (see 1.1) and rest it on the cut surface.

Real time varus/valgus, real time flexion and resected bone are displayed on screen.

F4 on the « cut plane » check-box registers the position of the template and validates the cut. The navigator will then display the validated varus/valgus, the validated flexion and the amount of bone resected from each condyle, while keeping real-time values active



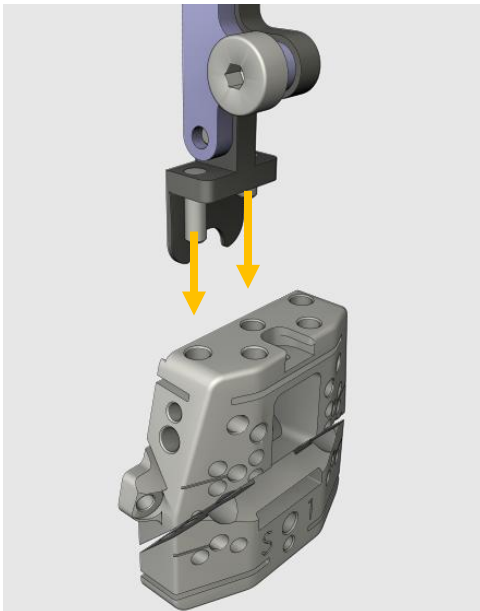
**It is extremely important to position the reference array correctly and to acquire the real data: the next steps depend on this acquisition, and a deviation from the real values may lead to errors.**

## 16. 4IN1 FEMORAL RESECTIONS



For the 4in1 cutting blocks ref.no. 02.07.10.2101-6 and 2.631-6 and the 4in1 CAS positioner ref.no. 2.637 please refer to Appendix 2.

### 16.1. ASSEMBLING THE G-ARRAY ON THE 4IN1 CUTTING BLOCK



#### **[02.07.10.0201-6]**

The same block is used on a left or a right femur.

Five holes are located on the top of the cutting block. The G-array must be inserted in the two medial ones (in the picture on the left, G-array assembly for a LEFT knee is displayed).

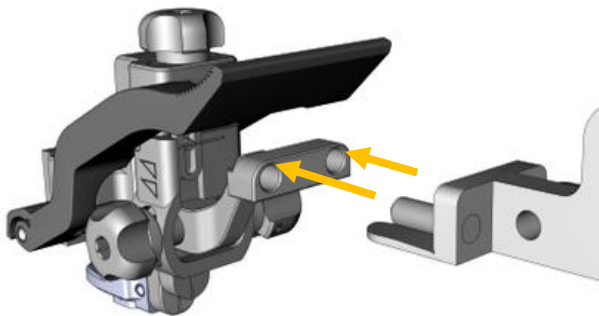
#### **MSS**

The cutting blocks ref.no. 02.07.10.0201-6 are suitable also for muscle sparing approaches.

### 16.2. THE CAS 4IN1 POSITIONER

The CAS 4in1 positioner allows the micrometric placement of the 4in1 cutting block, by adjusting cut height and external rotation. It is available in different versions depending on the 4in1 cutting block to be navigated.

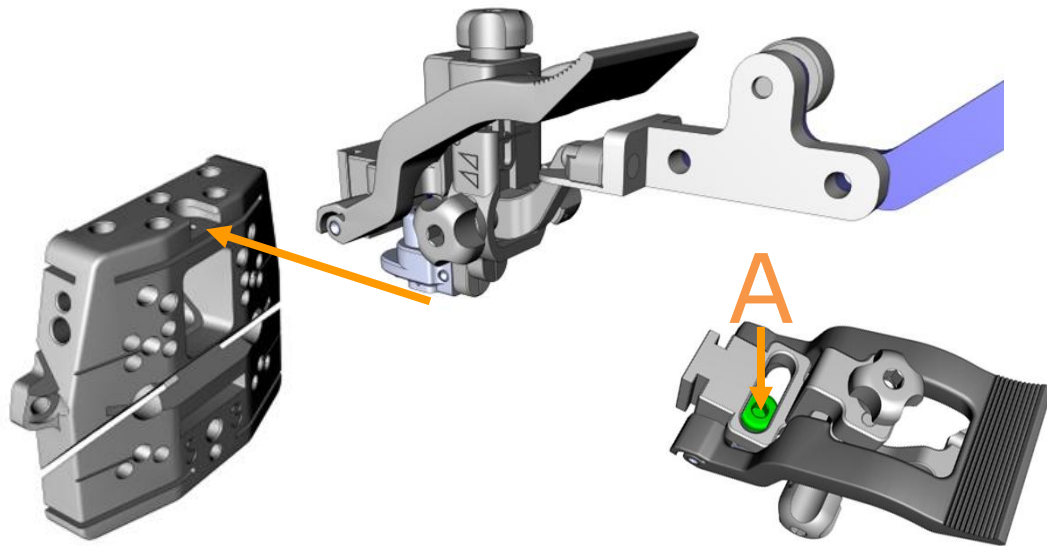
### 16.3. ASSEMBLING THE G-ARRAY ON THE 4IN1 MICROMETRIC POSITIONER



**[CAS 33.22.0137]**

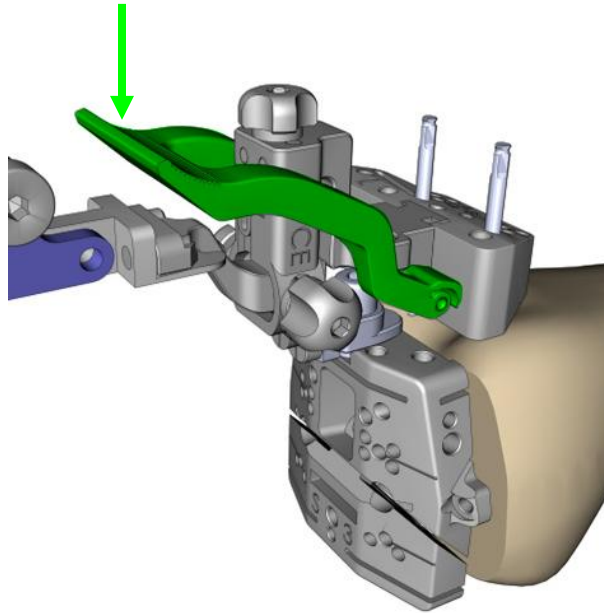
Insert the G-array in the two holes as displayed in the picture on the left.

### 16.4. ASSEMBLING THE 4IN1 CUTTING BLOCK ON THE 4IN1 MICROMETRIC POSITIONER



Slide the connection plate located on the bottom of the 4in1 positioner into the corresponding slot on the top of the 4in1 cutting block and turn the locking screw (A in the picture above, right) to secure the connection.

## 16.5. POSITIONING THE ASSEMBLY 4IN1 CUTTING BLOCK + 4IN1 POSITIONER ON THE FEMUR



The distal cutting block must be firmly in place in the same position it was when the distal resection was performed.

---

**TIP: Before fixing the 4in1 positioner on the distal block, set the regulation screws in the middle position in order to have the possibility to fine tune the block position in both directions.**

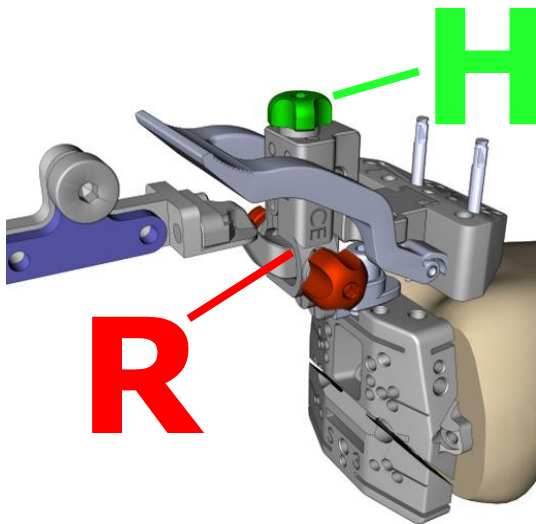
---

Slide the assembly on the connection plate located on the 4in1 positioner into the slot on the distal block and put the lever down (in the figure above, green) to secure the connection.

Make sure that the G-array is fully inserted in the appropriate position and using the data provided by the navigator, fine-tune the position of the block (see 16.8).

## 16.6. MICROMETRIC ADJUSTMENTS USING THE 4IN1 MICROMETRIC POSITIONER

The 4in1 CAS positioner allows micrometric fine tuning of the anterior/posterior cuts parameters. Adjustments are performed by turning specific knobs under computer assistance, as indicated in the figure below (pins fixation option).

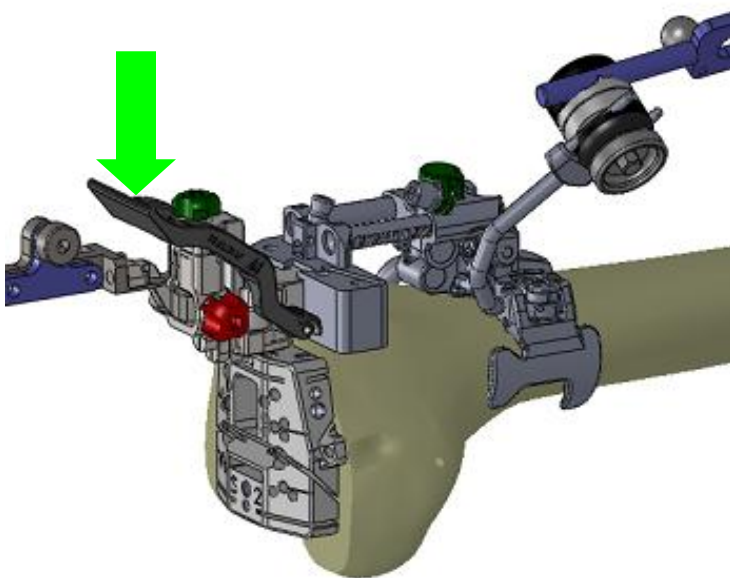


**[CAS 33.22.0137]**

H: Cut height adjustment

R: External rotation adjustment

## 16.7. POSITIONING THE ASSEMBLY 4IN1 CUTTING BLOCK + 4IN1 POSITIONER ON THE FEMORAL CLAMP



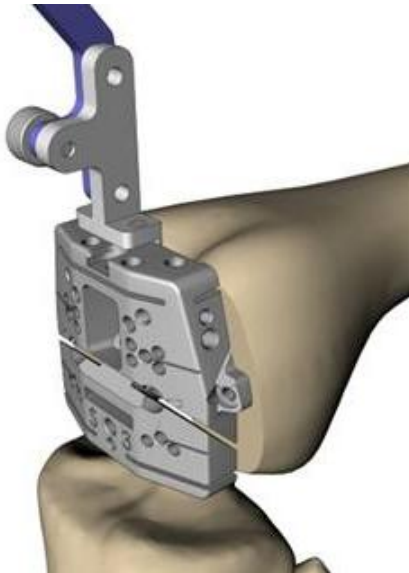
Connect the 4in1 positioner on the 4in1 cutting block (see par. 16.4)

Slide the 4in1 micrometric positioner on the micrometrical distal cutting block fixed on the femoral clamp and move the lever down to secure the connection (green arrow).

Under computer guidance, fine tune the 4in1 cutting block position as described in par. 16.6.

## 16.8. POSITIONING THE 4IN1 CUTTING BLOCK – FREEHAND

02.07.10.0201-6



It is possible to navigate the freehand positioning of the 4in1 cutting block. To do so, assemble the G-array on the block, as described in 16.1.

Rest the block on the distal resection surface and, under computer guidance, fine-tune the positioning.

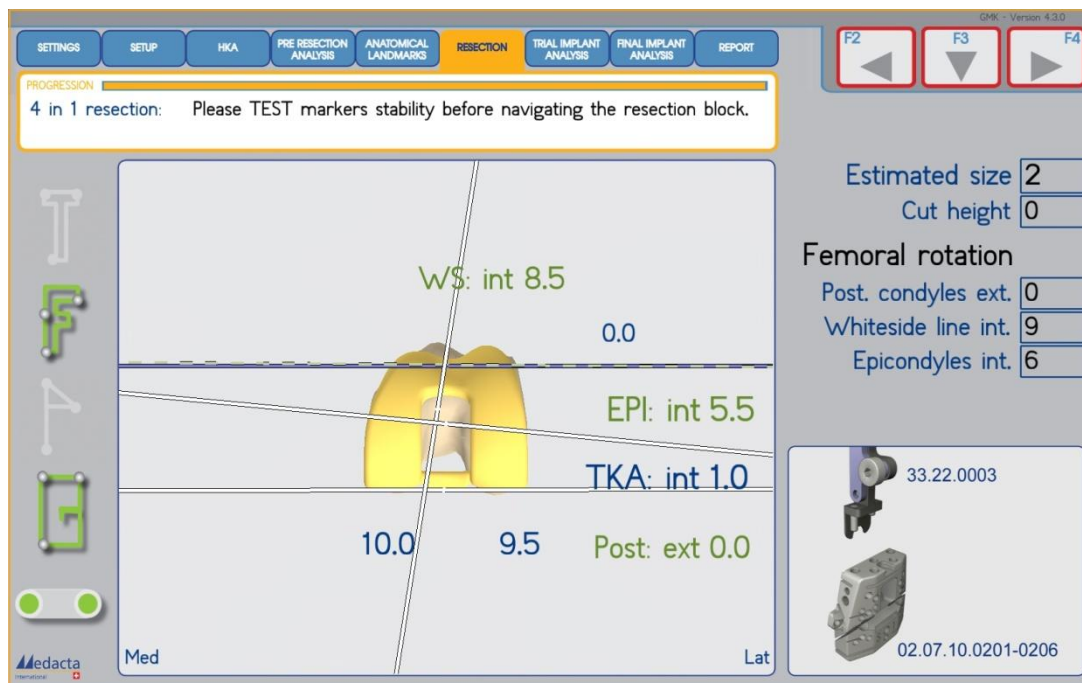
## 16.9. NAVIGATING THE 4IN1 FEMORAL RESECTION



**Before proceeding with the navigation of the resection block it is advisable to perform a confidence test on T and F arrays.**

Suggested prosthesis size is based on femoral A/P dimensions. If the suggested femoral component is wider than the femoral M/L landmarks acquired in « *FEMORAL LANDMARKS ACQUISITION* » the system will display a warning message « *WARNING – The prosthesis could be too wide* ». It is up to the user to decide to keep the suggested size or select a smaller prosthesis and remove greater amount of bone from the post condyles.

The size of the selected femoral component is displayed in shaded yellow, centered on the point registered as « femur center ».



Up to four fixed reference lines are displayed on screen:

Blue: planned anterior resection level

White: posterior condylar axis/ Whiteside's line / Epicondylar axis / TKA (i.e.tibia knee axis) (depending on the previously acquired landmarks).

A moving line informs the user about the real time positioning of the anterior cut plane during navigation of the cutting block.

The arrow symbol and the numerical value inform the user about the current difference in cut height with respect to the planned resection level. An arrow pointing down means that the current positioning of the cutting block is more posterior than the planned resection level (more bone will be resected from the anterior femur).

Below each condyle a numerical value informs the user in real-time about the amount of bone going to be cut from each post condyle.

The real time rotation vs posterior condyles line (*Post*), transepicondylar axis (*EPI*) and Whiteside's line (*WS*) is also shown on screen.



**It is advisable to always check the cut, using the conventional instruments, before resecting.**

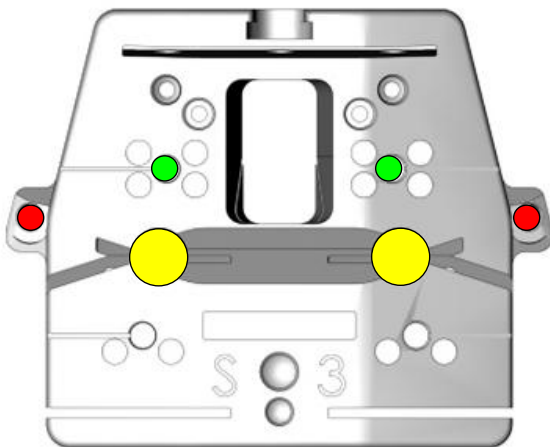


In case "CAS Positioner" was selected in the "Navigation settings" screen, an additional (optional) verification feature is available. Move the cursor to the picture icon the lower right corner of the screen, press f4 to switch the instrument in use from the CAS Positioner to the corresponding 4in1 block and accordingly assemble the G-array on the 4in1 block. Check the alignment of the block by reading on screen values.

---

#### 16.10. SECURING THE 4in1 RESECTION BLOCKS

Once the positioning of the block is deemed satisfactory, it can be stabilized using parallel pins, that still allow a correction of cut height, and an oblique pin to firmly hold the block in position. The following diagrams display the layout of the pin holes, 3.2 mm diameter pins are used.



4in1 BLOCK  
(02.07.10.0201-6)

Green: parallel pins  
Red: oblique pin  
Yellow: cancellous bone screws



It is advisable to insert the pins under power control, to avoid pinning the block in malalignment. Ensure low drilling speed to reduce heat generation.

---

## **16.11. 4IN1 FEMORAL RESECTIONS**

Before performing the resections, tools that could interfere with the saw blade must be removed.

Check the final alignment of the block and gently remove the G-array.

---



**It is suggested to double check the cut by means of the conventional sickle finger before cutting.**

---

Insert the saw blade guide on the standard block to ensure a more accurate resection and, using a 1.27 mm blade, accurately resect the bone, taking care protecting soft tissue from injury.

The following cutting sequence is suggested:

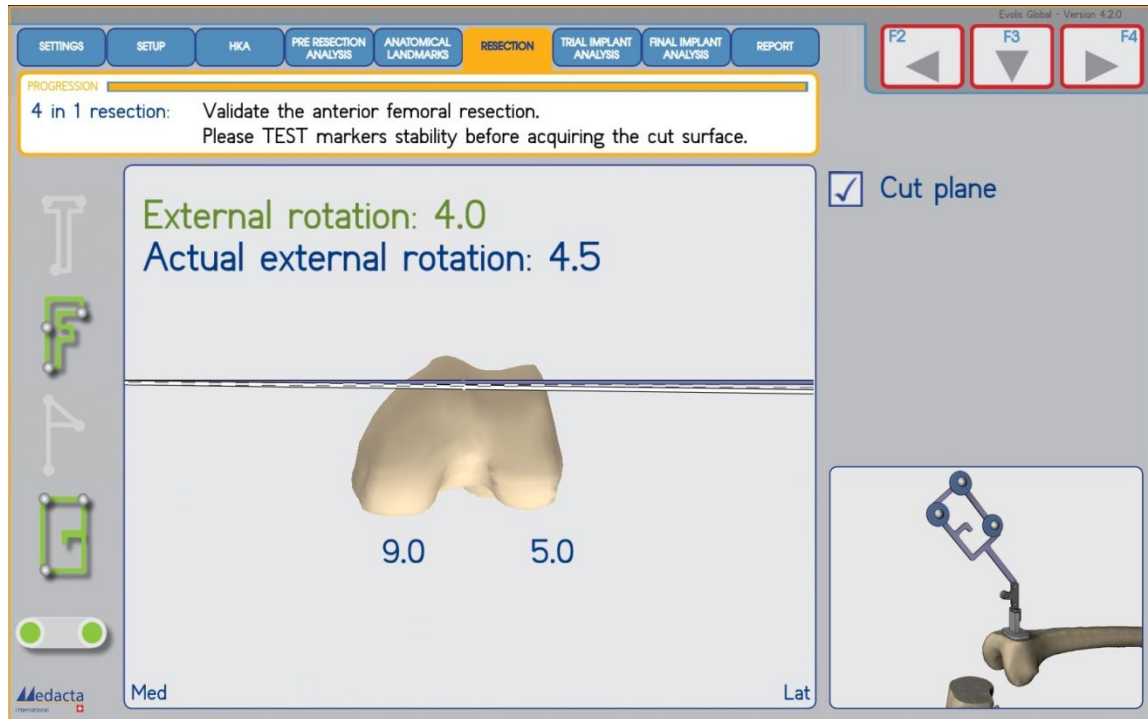
- Anterior cut
- Posterior cut
- Posterior chamfer cut
- Anterior chamfer cut



**Femoral resections using 4in1 cutting blocks ref.no. 02.07.0201-6 require 13 mm wide blades.**

---

## 16.12. ANTERIOR FEMORAL RESECTION VALIDATION [Option]



**Before validating the resection plane it is advisable to perform a confidence test on T and F arrays.**

Assemble the "G" array on the verification template (see 8.4) and rest it on the cut surface.

*Real time* external rotation and posterior cuts height are displayed on screen.

F4 on the « validate » check-box registers the position of the template and validates the cut. The navigator will then display the validated external rotation related to the posterior condyles line.



**It is extremely important to position the reference array correctly and to acquire the real data: the next steps depend on this acquisition, and a deviation from the real values may lead to errors.**

## 17. TIBIAL RESECTION

*Option*

For the tibial cutting blocks ref.no. 02.07.10.2145/6 and 2.622 please refer to Appendix 3.

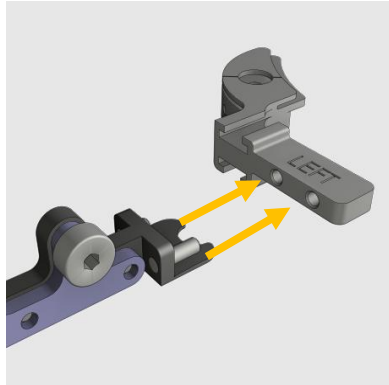
### 17.1. ASSEMBLING THE G-ARRAY ON THE TIBIAL CUTTING BLOCK



#### **[STD. 02.07.10.0111/3]**

Select the appropriate cutting block (Left or Right, according to the knee undergoing surgery) and insert the G-array in the two dedicated holes.

MSS

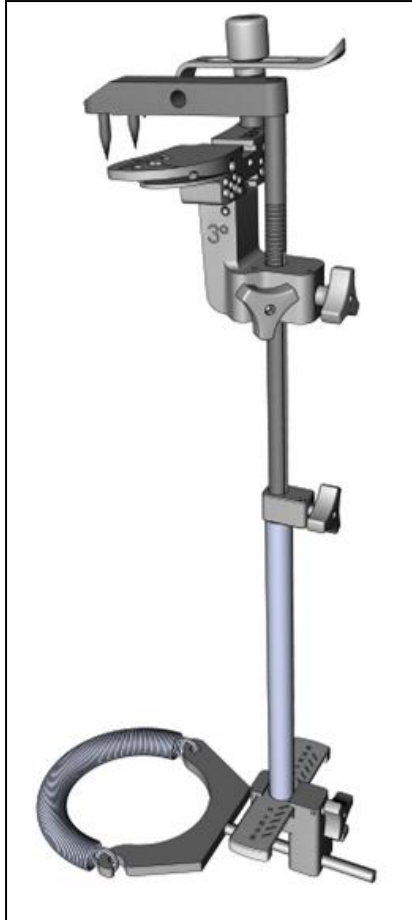


#### **[MIS 02.07.10.0290/1]**

Two blocks are available for a left or right knee. Chose the correct block and insert the G-array in the two dedicated holes as shown in the picture.

## 17.2. ASSEMBLING THE TIBIAL CUTTING BLOCK ON THE EXTRAMEDULLARY ALIGNMENT JIG

**STD 02.07.10.0111/3**



**MSS**

**MIS 02.07.10.0290/1**

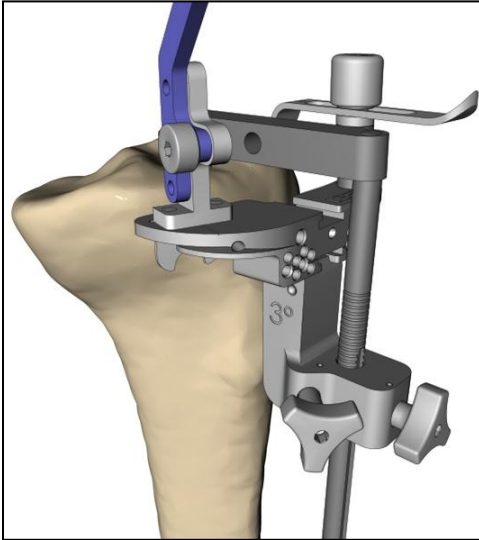


The standard and MIS tibial cutting blocks can be assembled on the extramedullary alignment jig. The advantage of using this instrumentation in conjunction with navigation is a higher stability of the block during the positioning phase.

The stylus can optionally be used to estimate the depth of the resection (see conventional surgical technique).

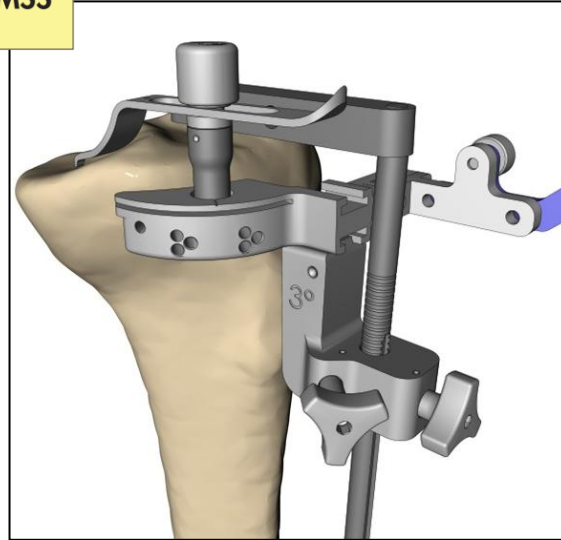
### 17.3. POSITIONING THE TIBIAL CUTTING BLOCK – EXTRAMEDULLARY JIG OPTION

**STD 02.07.10.0111/3**



**MSS**

**MIS 02.07.10.0290/1**



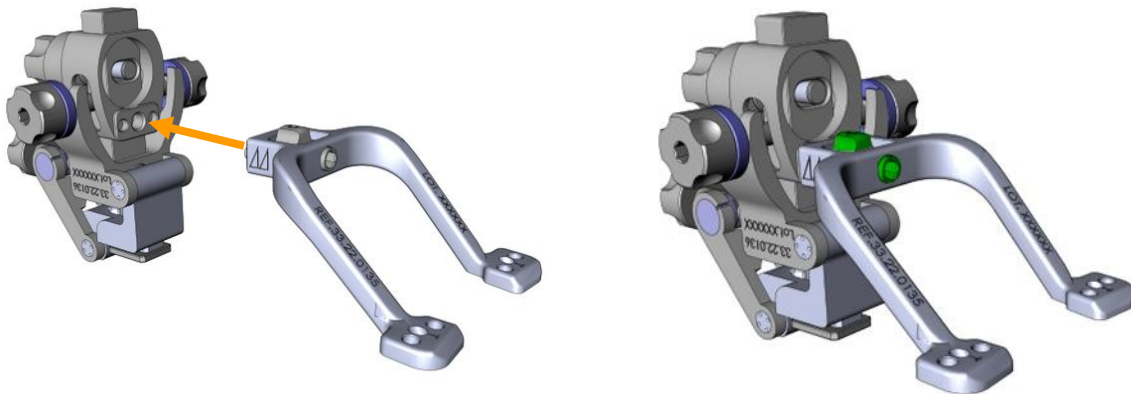
To navigate the positioning of the tibial cutting block when the extramedullary jig is used insert the G-array on the cutting block and position the lower part of the jig taking care that the malleolar pincer is exactly facing the centre of the ankle joint. Let the upper and lower part of the jig free to slide into each other.

Under computer guidance it will then be possible to fine-tune the placement of the block.

#### **17.4. POSITIONING THE TIBIAL CUTTING BLOCK – DT MICROMETRIC POSITIONER**

The DT - micrometric positioner can be fixed on the tibia by mean of the DT - micrometric support.

##### **17.4.1. ASSEMBLING THE DT - MICROMETRIC POSITIONER ON THE DT - MICROMETRIC SUPPORT**



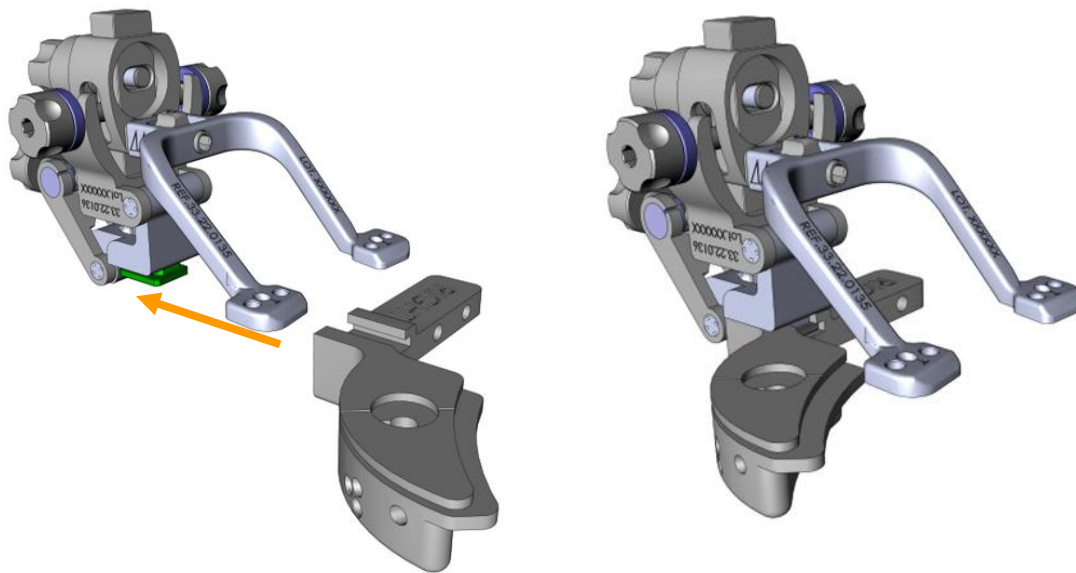
The following components of the micrometric system must be assembled to navigate the tibial resection:

- DT - Micrometric Positioner (33.22.0136)
- DT - Micrometric Support (33.22.0135).

Assemble the micrometric support on the 3-hole socket on the micrometric positioner, as indicated in the picture above on the left. Secure the assembly by turning the knob highlighted in green in the picture above on the right.

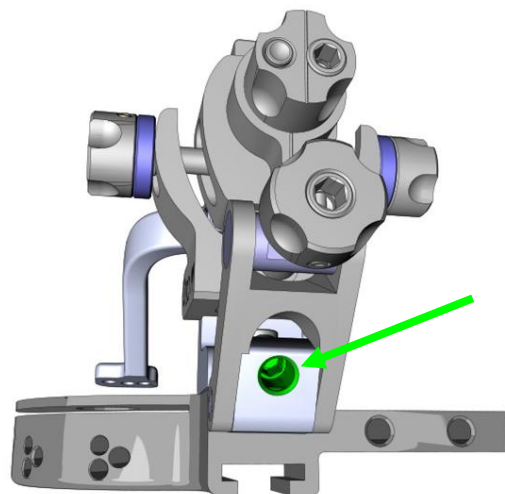
## 17.4.2. ASSEMBLING THE TIBIAL CUTTING BLOCK ON THE DT - MICROMETRIC POSITIONER

**TIP:** Before fixing the micrometric positioner on the distal block, set the regulation screws in the middle position in order to have the possibility to fine tune the block position in both directions.



Locate the flat coupling surface on the DT - micrometric positioner (in green in figure above, left) and slide the selected tibial resection block on it. - Figures above, display the assembling of a right MIS tibial resection block.-

Once the block is fully inserted in position (see figure above, right), secure the assembly by tightening the locking knob (highlighted in green in the picture aside).



### 17.4.3. POSITIONING THE ASSEMBLY TIBIAL RESECTION BLOCK + DT MICROMETRIC POSITIONER ON THE TIBIA

Assemble G-shaped array on the selected tibial cutting block (see 17.1) and make sure that the latter is firmly attached to the micrometric positioner. Before navigating the block, set the parameters (see 17.4.4) close to the target position and finally fix the DT - micrometric support to the tibial plateaus by inserting two 3.2 mm pins in the dedicated holes.

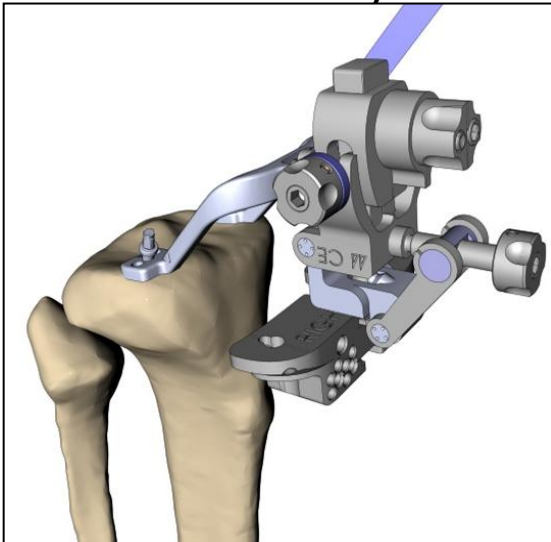
The following pin holes can be used:



Green: tibial pins

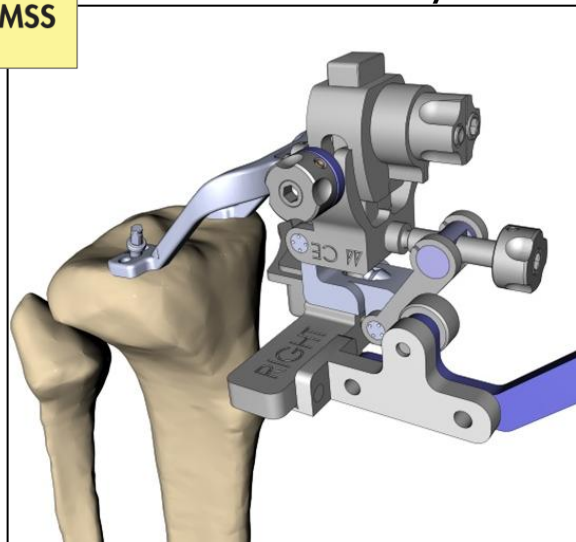
Under computer guidance it will then be possible to fine-tune the placement of the block using the micrometric adjustments. The following pictures illustrate the positioning on a right knee.

**STD 02.07.10.0111/3**



MSS

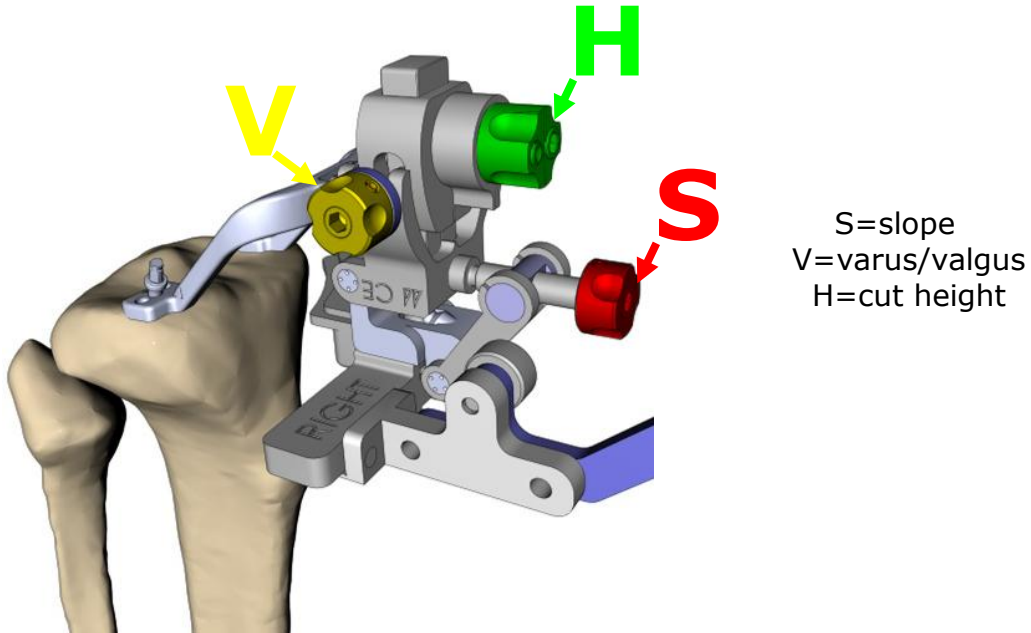
**MIS 02.07.10.0290/1**



#### 17.4.4. MICROMETRIC ADJUSTMENTS USING THE DT MICROMETRIC POSITIONER

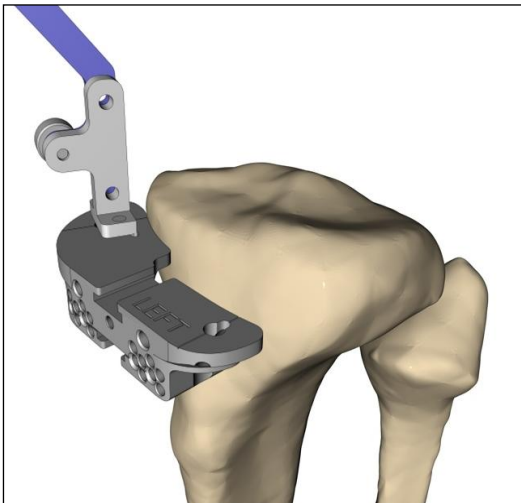
The DT - micrometric positioner allows micrometric fine tuning of the cut position of the block.

Adjustments are performed by turning specific knobs under computer assistance, as indicated in the figures below:

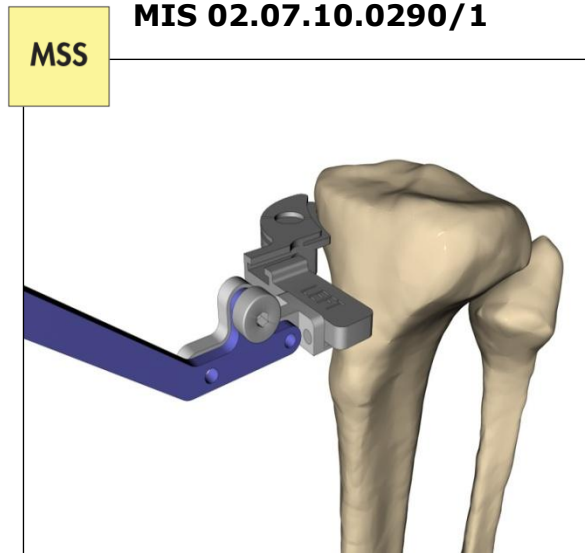


#### 17.5. POSITIONING THE TIBIAL CUTTING BLOCK – FREEHAND

**STD 02.07.10.0111/3**

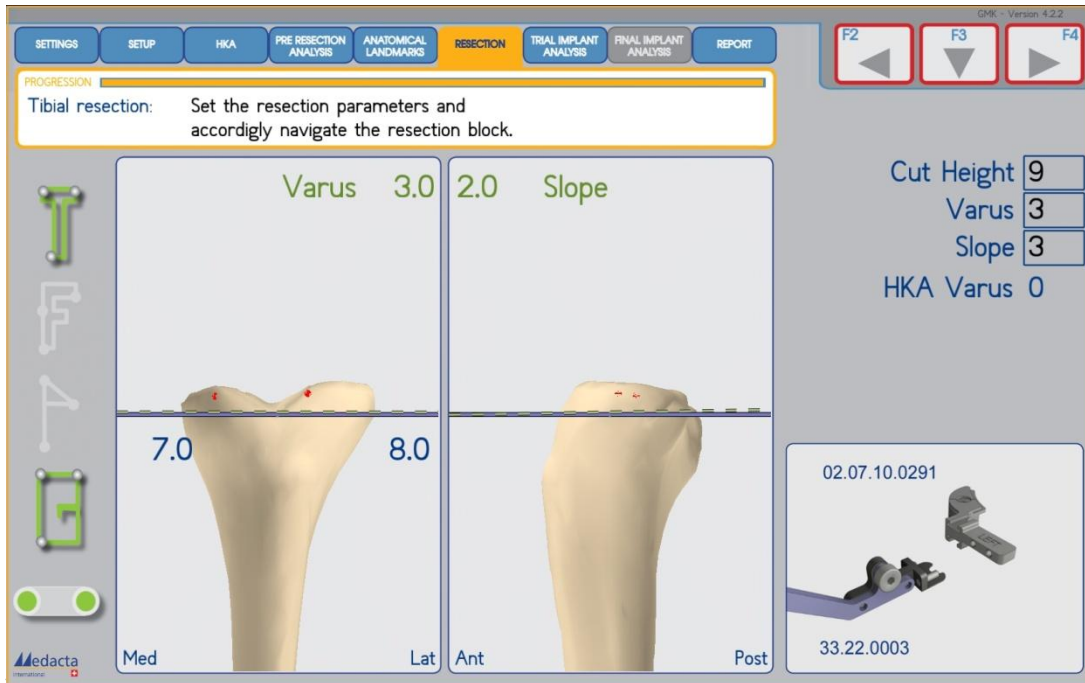


**MIS 02.07.10.0290/1**



It is possible to navigate the freehand positioning of the tibial cutting block. To do so, assemble the G-array on the block, as described in 17.1. Rest the block on the tibia and, under computer guidance, fine-tune the positioning.

## 17.6. NAVIGATING THE TIBIAL RESECTION



**Before proceeding with the navigation of the resection block it is advisable to perform a confidence test on T and F arrays.**

---

Assemble the « G » array on the tibial cutting block.

Standard resection parameters are displayed on the right. They can be altered according to the surgeon's needs. This operation will move the bone model displayed on screen so that its orientation with respect to the "target" blue lines is accordingly updated.

Real time numerical values in the front view of the tibia indicate the current cut height relative to the deepest point of each plateau. Real-time values on top show varus/valgus and slope of the cutting block.



**It is advisable to always check the cut, using the conventional instruments, before resecting.**

---



The numerical value in the field HKA (Hip-Knee-Ankle axis) Varus/Valgus is calculated as:

***Validated Distal V/v + Planned tibial V/v.***

HKA Varus/Valgus equals 0 if the planned tibial resection compensates the validated distal resection.

---



The field HKA Varus/Valgus will not be displayed in case a tibia-first procedure was selected.

---



The number in the numerical box "*Cut height*" always indicates the cutting height with respect to the tibial plateau selected as reference (see "*Navigation settings*").

---



The tibial slope must be set up before setting the level of the cut.

Any degree of anterior slope must be avoided.

An excessive slope could damage the tibial insertion of the posterior cruciate ligament in case a **STD INSERT** is used.

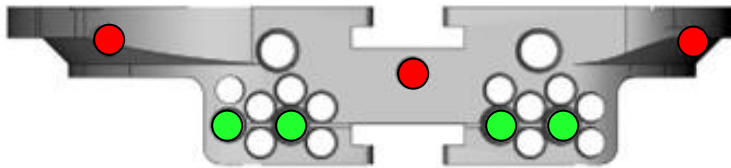
**STD INSERT**: To protect the PCL, 1 or 2 x 2.7 mm diameters nails may be fixed in front of the tibial insertion of the PCL before proceeding with the tibial resection

**STD AND PS INSERTS**: In case of a tibial cut with slope, ensure that there is no rotation of the tibial resection guide.

---

## 17.7. SECURING THE TIBIAL RESECTION BLOCKS

Once the positioning of the block is deemed satisfactory, it can be stabilized using parallel pins, that still allow a correction of cut height, an oblique pins to firmly hold the block in position. The following diagrams display the layout of the pin holes, 3.2 mm diameter pins are used.



STANDARD BLOCK (STD  
02.07.10.0111/3)  
left knee  
Green: parallel pins  
Red: oblique pin

MSS



MIS BLOCK  
(MIS 02.07.10.0290/1)  
left knee  
Green: parallel pins  
Red: oblique pin



**It is advisable to insert the pins under power control, to avoid pinning the block in malalignment. Ensure low drilling speed to reduce heat generation.**

## 17.8. TIBIAL RESECTION

Before performing the resection, tools that could interfere with the blade must be removed.

Check the final alignment of the block and gently remove the G-array.

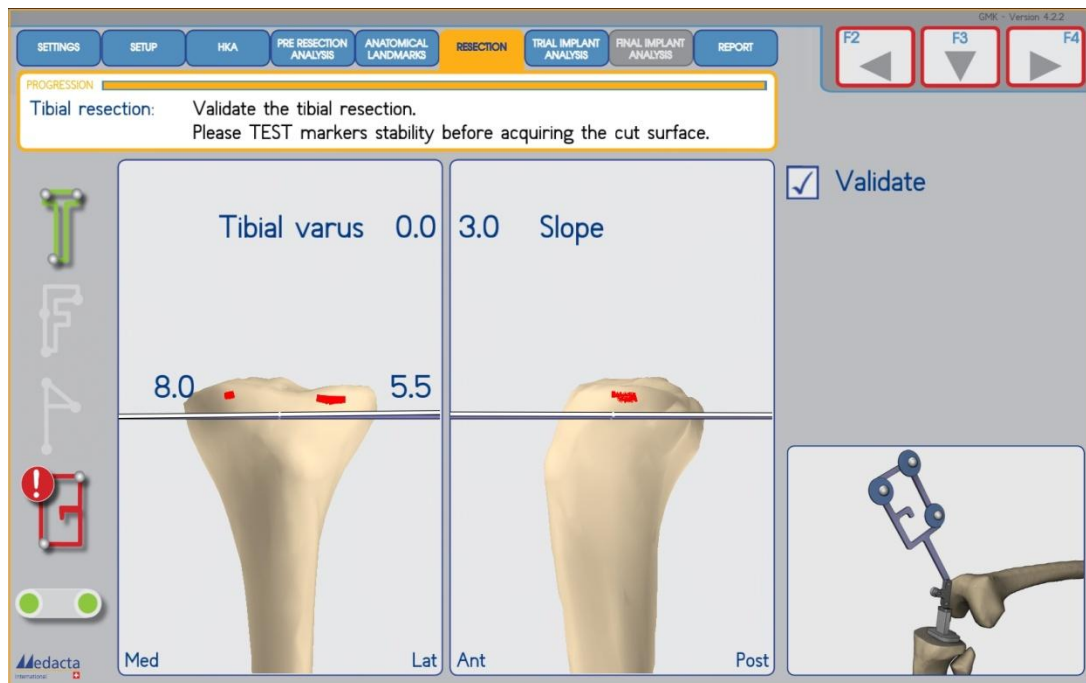
Insert the saw blade guide on the standard block for a more accurate resection and, using a 1.27 mm blade, accurately resect the bone, taking care protecting soft tissue from injury.

## 17.9. TIBIAL RESECTION VALIDATION *[Option]*



**Before validating the resection plane it is advisable to perform a confidence test on T and F arrays.**

Assemble the “G” array on the verification template and rest it on the cut surface.



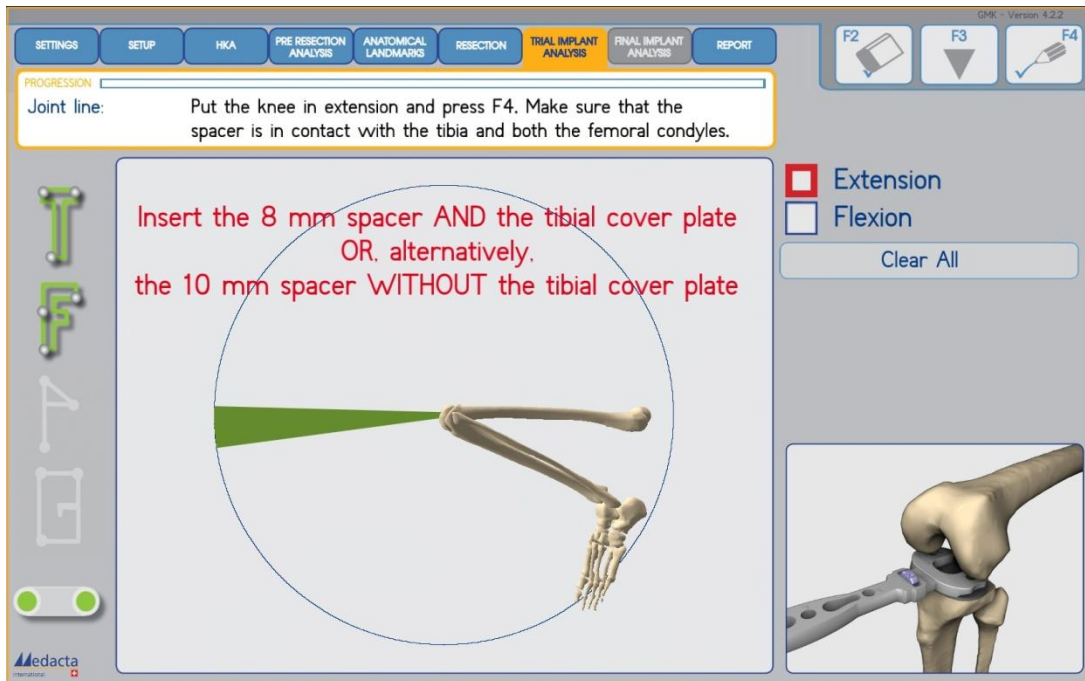
*Real time* varus/valgus posterior slope and cut heights are displayed on screen.

F4 on the « validate » check-box registers the position of the template and validates the cut. The navigator will then display the validated varus/valgus and slope and the amount of bone resected from each plateau.



**It is extremely important to position the reference array correctly and to acquire the real data: the next steps depend on this acquisition, and a deviation from the real values may lead to errors.**

## 17.10. JOINT LINE FINE-TUNING (only for tibia-first technique)



This step refines the position of the joint line after the tibial resection.



**The simulation of the 10 mm minimum gap is MANDATORY.**

The spacer must be inserted into the joint before performing the acquisitions in extension and flexion.

The 10 mm gap can be obtained by mean of two different combinations, as suggested on screen:

- 2 mm tibial cover plate [Ref.no. 02.07.10.2305-7, depending on tibial size] + IC reference spacer [Ref.no. 02.07.10.2230] mounted on the dedicated handle [Ref.no. 02.07.10.1027].
- 10 mm spacer [Ref.no. 02.07.10.4710 or 02.07.10.4810, depending on tibial size] + IC reference spacer [Ref.no. 02.07.10.2230] mounted on the dedicated handle [Ref.no. 02.07.10.1027].

Make sure that the distal (posterior) condyles, as well as the tibia, are firmly in contact with the spacer when acquiring.



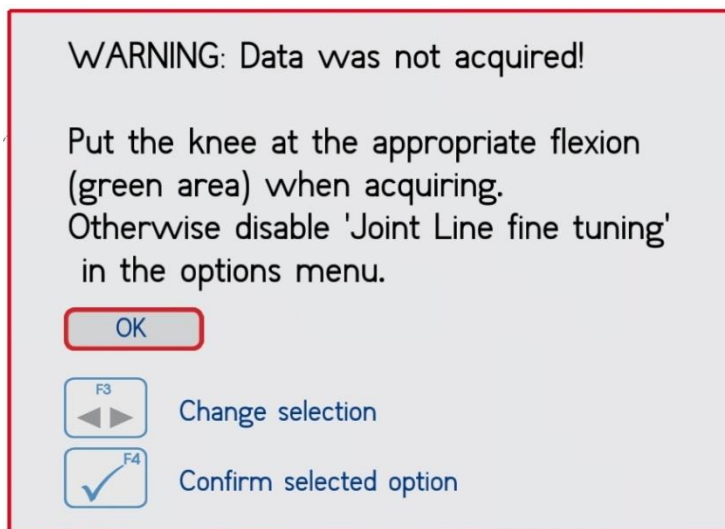
**If the joint line fine-tuning is not properly done, femoral resections will be adversely affected thus making navigation unreliable**



**This step is NOT for ligament balancing purposes. Even though the 10 mm spacer appears inadequate to correctly fill the joint gap, DO NOT USE A THICKER SPACER when fine-tuning the joint line.**



**Make sure to perform each acquisition at the required extension/flexion (green area on screen). If the required extension/flexion can't be reached, the following message will be displayed on screen.**

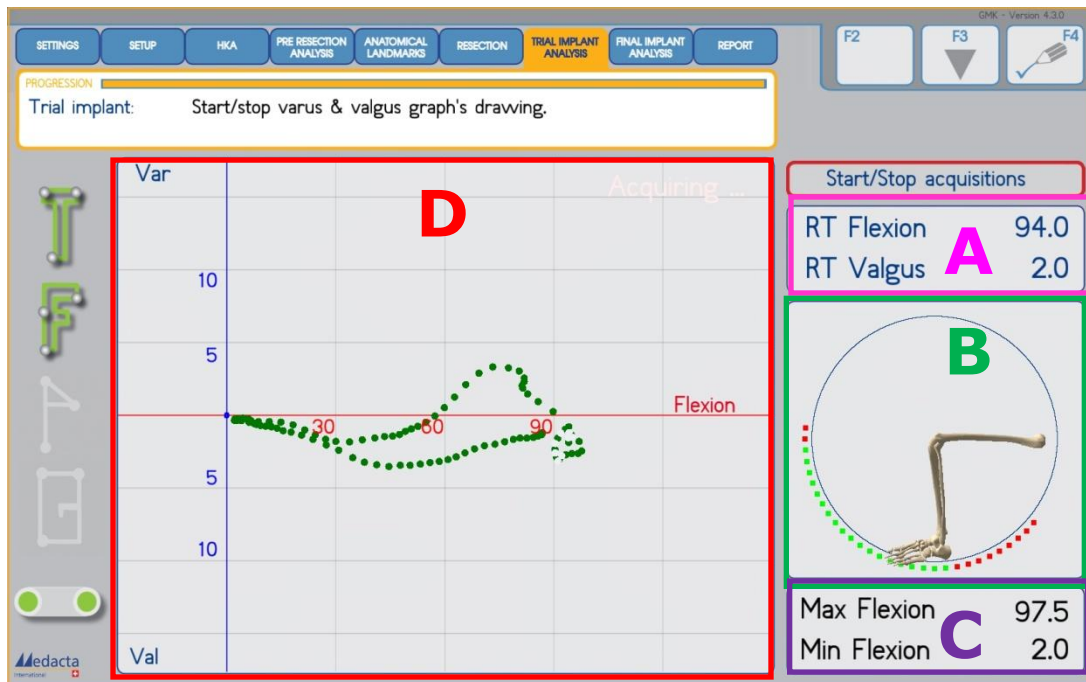


If it is impossible to reach the required extension/flexion and no surgical modification of flexion/extension gap is deemed necessary, come back to the "Navigation settings" screen (by pressing f6) and disable the "Joint line fine tuning" option.

## 17.11. IMPLANTATION

### 17.11.1. TRIAL IMPLANT ANALYSIS

This step allows performing kinematic analysis of the knee along the entire range of motion (ROM) as a result of the trial components placement. Current varus/valgus values at different flexion angles are plotted on screen.



#### A: REAL-TIME (RT) DATA

Real time flexion and varus/valgus are displayed and constantly updated.

#### B: ROM INDICATOR

The range of motion is segmented in sectors of 5 degrees, indicated by the colored squares. Squares are initially red and become green once the corresponding varus/valgus sample has been recorded.

#### C: MAX VALUES

Maximum and minimum flexion (i.e. maximum extension) are displayed here.

#### D: PLOT AREA

Kinematics of the knee joint are plotted using green dots (real-time).

x-axis (horizontal): flexion angle. Each unit of the grid corresponds to 30 degrees

y-axis (vertical): varus (upper half) and valgus (lower half). Each unit of the grid corresponds to 5 degrees

Press f4 to activate "*START/STOP acquisitions*" and begin registering data. A higher "BUZZ" sound will inform the user when the acquisition is ongoing, a lower "BUZZ" sound will inform the user if one of the arrays is not visible during acquisition. In this case the acquisition will be stopped until all the arrays are visible again.

Once the wished data have been registered press f4 again to stop registration. A snapshot will be automatically taken and the cursor will move to the navigation box.

To acquire a new graph, move the cursor to "*START/STOP acquisitions*" and press f4.



**Please note that the previous graph will be deleted but any existing snapshot will be kept in memory.**

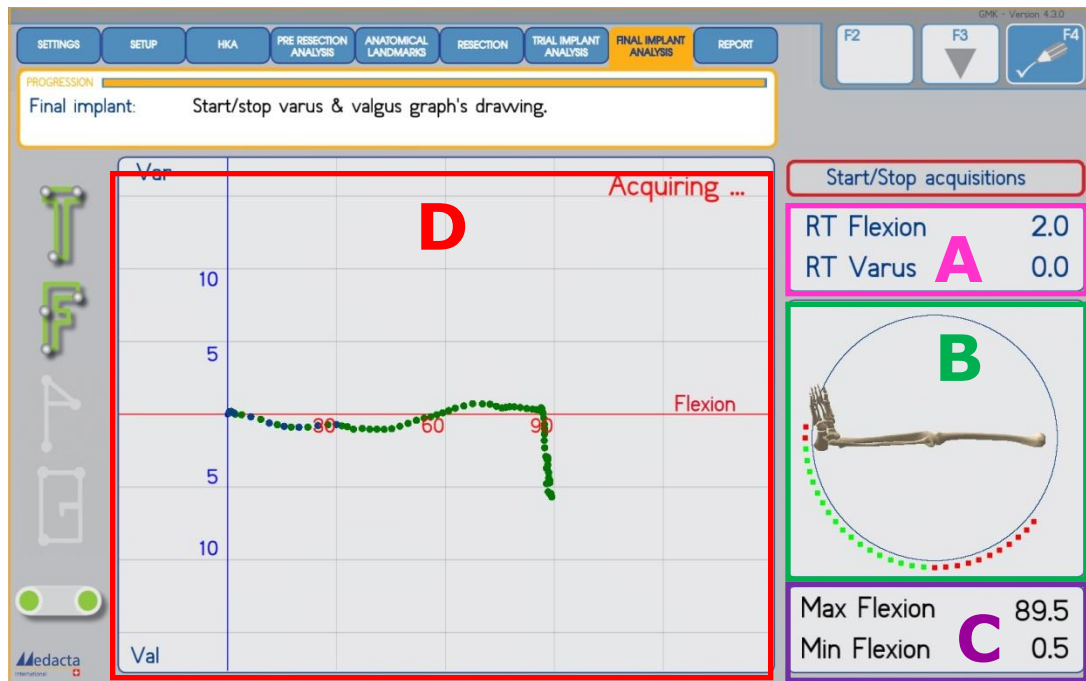
---

### 17.11.2. FINAL IMPLANT ANALYSIS

This step allows performing kinematic analysis of the knee along the entire range of motion (ROM) as a result of the final components placement. Current varus/valgus values at different flexion angles are plotted on screen.

#### C: MAX VALUES

Maximum and minimum flexion (i.e. maximum extension) are displayed here.



#### A: REAL-TIME (RT) DATA

Real time flexion and varus/valgus are displayed and constantly updated.

#### B: ROM INDICATOR

The range of motion is segmented in sectors of 5 degrees, indicated by the colored squares. Squares are initially red and become green once the corresponding varus/valgus sample has been recorded.

#### C: MAX VALUES

Maximum and minimum flexion (i.e. maximum extension) are displayed here.

#### D: PLOT AREA

Kinematics of the knee joint are plotted using green dots (real-time).

x-axis (horizontal): flexion angle. Each unit of the grid corresponds to 30 degrees

y-axis (vertical): varus (upper half) and valgus (lower half). Each unit of the grid corresponds to 5 degrees.

Press f4 to activate "*START/STOP acquisitions*" and begin registering data. A higher "BUZZ" sound will inform the user when the acquisition is ongoing, a lower "BUZZ" sound will inform the user if one of the arrays is not visible during acquisition. In this case the acquisition will be stopped until all the arrays are visible again.

Once the wished data have been registered press f4 again to stop registration. A snapshot will be automatically taken and the cursor will move to the navigation box.

To acquire a new graph, move the cursor to "*START/STOP acquisitions*" and press f4.



**Please note that the previous graph will be deleted but any existing snapshot will be kept in memory.**

---

## 17.12. REPORT CREATION

GMK - Version 4.3.0

SETTINGS SETUP HKA PRE RESECTION ANALYSIS ANATOMICAL LANDMARKS RESECTION TRIAL IMPLANT ANALYSIS FINAL IMPLANT ANALYSIS REPORT

PROGRESSION

Create report: Insert the remarks on the surgery:

Medacta  
iMNS  
Medacta Navigation System  
GMK  
June 4, 2010

Patient Data

- ID: ...
- Name: ...
- Sex: ...
- Birth date: ...
- Weight: [kg] [mg]
- Height: [kg]
- BMI: ...

Surgery Data

General surgery data

|                    |        |
|--------------------|--------|
| Surgery name       | de VXX |
| Surgery type       | de VXX |
| Hydration material | de VXX |

Knee data

| Operated knee | LEFT KNEE | RIGHT KNEE |
|---------------|-----------|------------|
|               |           |            |

Navigation settings

|                                    | ENABLED | DISABLED |
|------------------------------------|---------|----------|
| Filter - Bone distal - Bone 4 in 1 | ✓       |          |
| Filter - Bone distal - Bone 4 in 1 |         | ✓        |
| Filter - Bone distal - Bone 4 in 1 |         | ✓        |

Remarks:

Write a comment

Create Report (store on CD)

Create Report (store on USB-DRIVE)

At the end of the procedure, the iMNS™ system can display a surgery report containing the pre-surgery and post-surgery data, as well as the personal data of the patient (if entered at the beginning of the procedure).

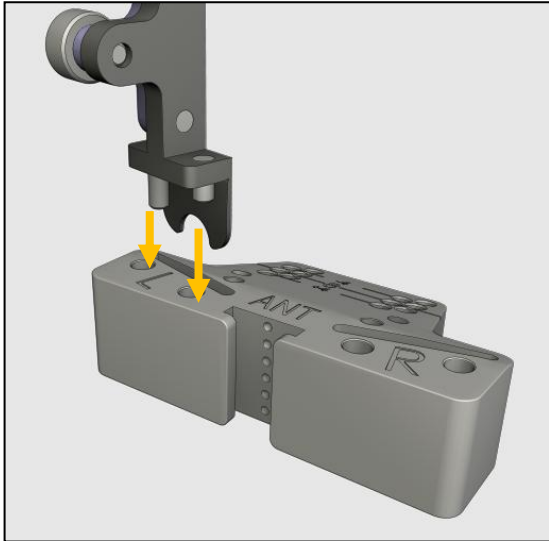
Prior to generating the report ("Create Report" control), the user can add annotations and remarks by typing text in the "Remarks" box, as displayed in the picture above.

When "Create Report" is activated, iMNS™ asks the user whether he/she wishes to save the data on CD or USB stick. If the answer is positive, insert the CD/USB stick in the drive to automatically save the previously displayed surgery report. In case of negative answer, the surgery is stored by default in the system memory and can be later retrieved.

The report is a multi-page document: after selecting the report, pressing F4 will display next page on screen.

## 18. APPENDIX 1 – OTHER DISTAL CUTTING BLOCKS

### 18.1. ASSEMBLING THE G-ARRAY ON THE DISTAL CUTTING BLOCK

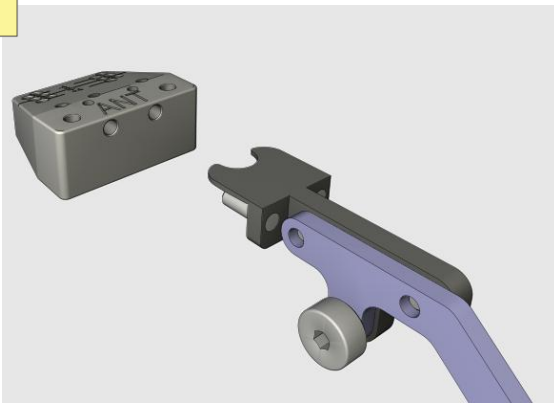


#### **[STD 2.623]**

The same block is used on a left or a right femur.

Insert the G-array in the two holes marked with an "L" –left knee- or an "R" –right knee-.

MSS

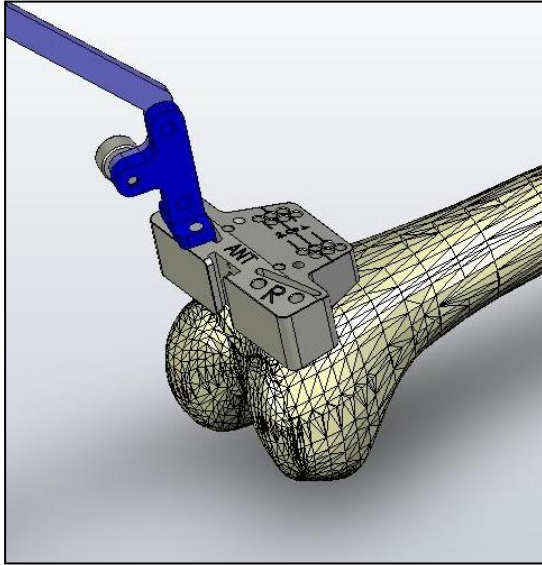


#### **[MIS 02.07.10.0065]**

The same block is used on a left or a right femur. Locate the upper face and insert the G-array in the two dedicated holes.

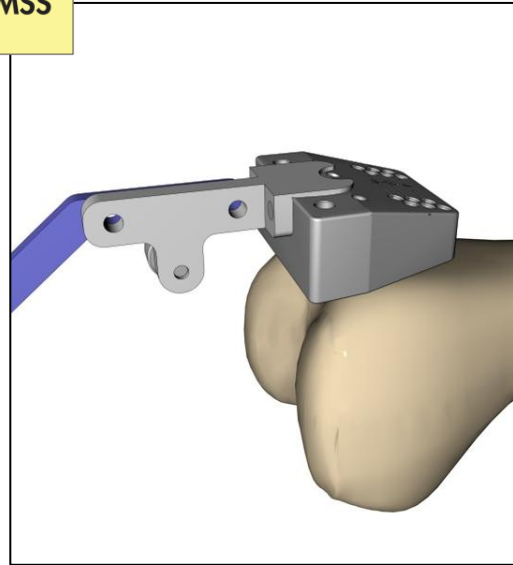
## 18.2. NAVIGATING THE DISTAL CUTTING BLOCK FREE-HAND

STD 2.623



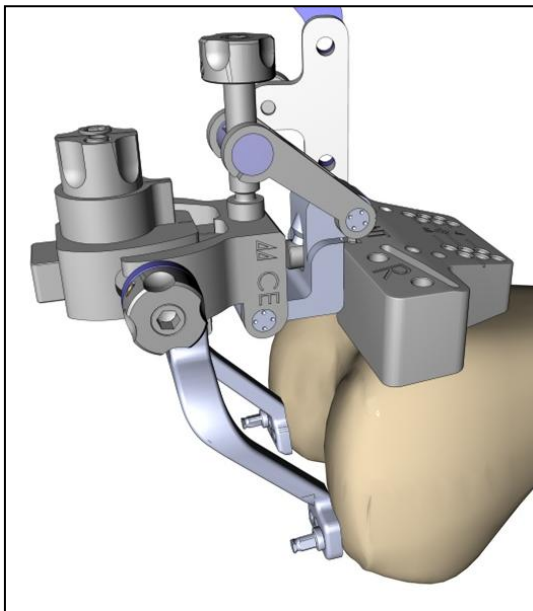
MSS

MIS 02.07.10.0065



Rest the selected distal cutting block on the anterior condyles and under computer assistance fine tune its position.

## 18.3. POSITIONING THE ASSEMBLY DT-MICROMETRIC POSITIONER + DISTAL CUTTING BLOCK ON FEMUR



Assemble the DT micrometric positioner and the DT micrometric support (see 15.2.1) then mount the distal cutting block on the assembly (see 15.2.2).

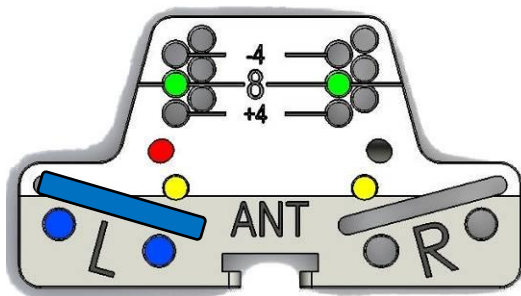
Position the assembly on femur - figure left- and fine tune the position of the block by mean of the micrometric positioner regulations (see 15.2.4).



**The distal cutting block ref. no. 02.07.10.0065 is not compatible with the fixation by mean of the micrometric positioner.**

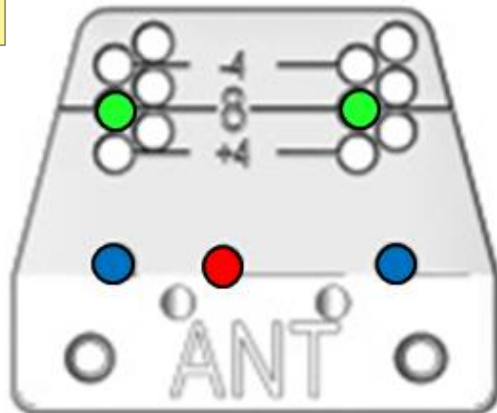
#### 18.4. SECURING THE DISTAL CUTTING BLOCKS

After positioning the block under computer assistance (see 15.4), secure it by mean of dedicated pins as shown in figures below.



STANDARD BLOCK  
(STD 2.623)– left knee  
Green: parallel pins  
Red: oblique pin  
Yellow: optional parallel pins  
Blue: G-array

MSS



(MIS 02.07.10.0065)  
Green: parallel pins  
Red: oblique pin  
Blue: optional parallel pins

After the block has been properly fixed, perform the distal resection (see 15.6) and finally validate the cut (see 15.7).

## 19. APPENDIX 2 – OTHER 4IN1 CUTTING BLOCKS

### 19.1. ASSEMBLING THE G-ARRAY ON THE 4IN1 CUTTING BLOCK



#### ***[STD 02.07.10.2101-6]***

The same block is used on a left or a right femur.

Insert the G-array in the two dedicated holes located on the top of the block.

MSS

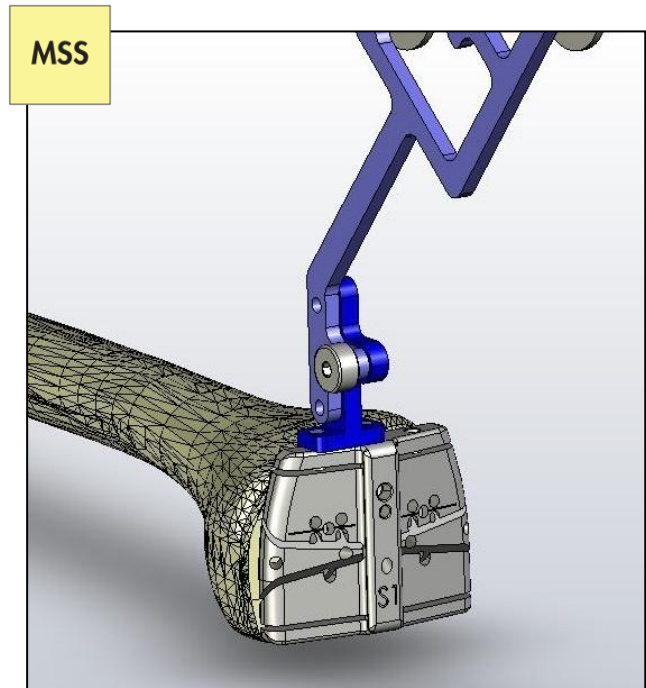
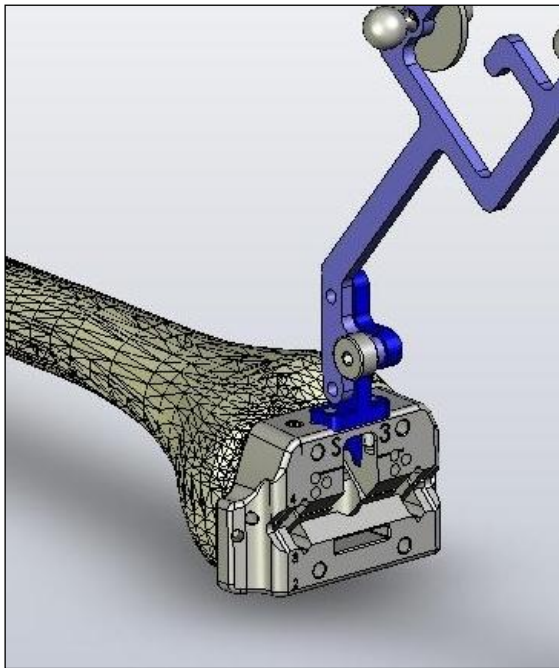


#### ***[MIS 2.631-6]***

The same block is used on a left or a right femur.

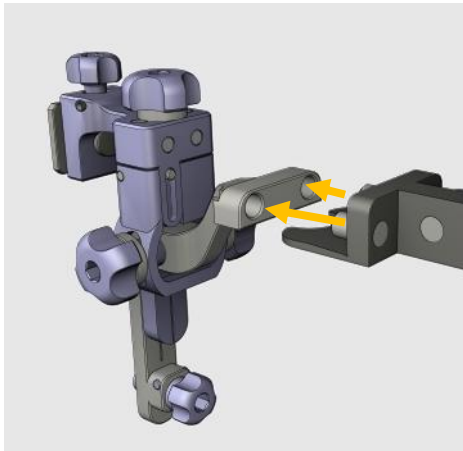
Three holes are located on the top of the cutting block. The G-array must be inserted in the two medial ones (in the picture on the left, G-array assembly for a LEFT knee is displayed).

## 19.2. NAVIGATING THE 4IN1 CUTTING BLOCK FREE-HAND



Rest the selected 4in1 cutting block on the performed distal cut and under computer assistance fine tune its position.

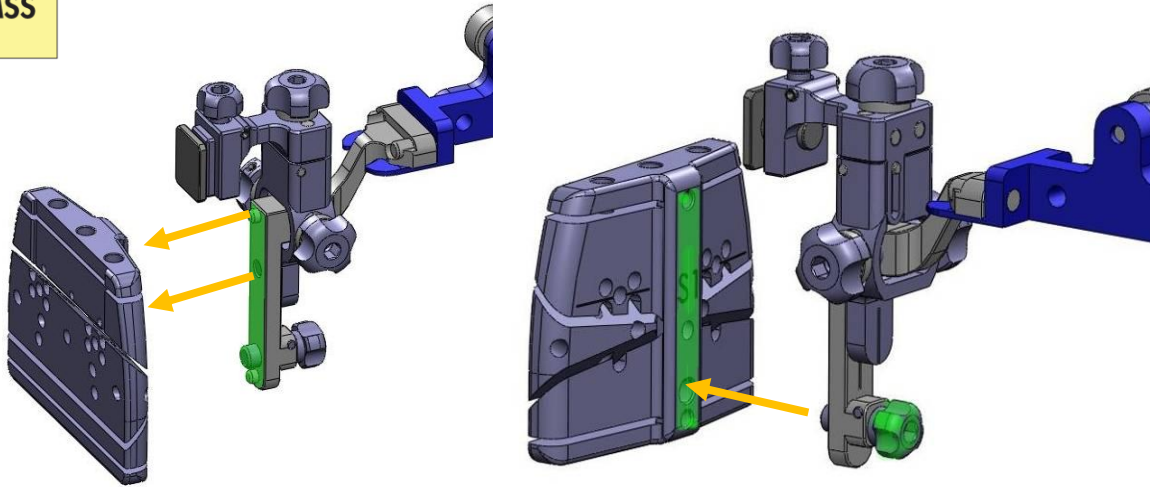
## 19.3. ASSEMBLING THE 4IN1 CAS POSITIONER ON THE 4IN1 CUTTING BLOCK



### **[CAS 2.637]**

Insert the G-array in the two holes as displayed in the picture on the left.

MSS



**[MIS 2.631-6]**

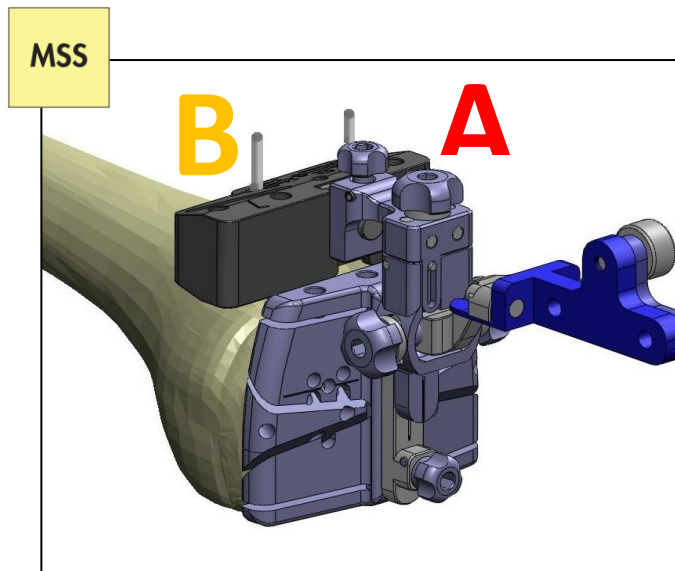
Insert the centering pins on the CAS positioner (see figure above, left) into the two holes located on the rib on the MIS 4in1 cutting blocks (figure above, right). Apply pressure so that the block and the positioner are in full contact and secure the assembly by turning the knob highlighted in green in the picture above, right.



**The 4in1 cutting blocks ref. no. 02.07.10.2101-6 are not compatible with the fixation by means of the micrometric 4in1 positioner ref.no. 33.22.0137.**

## 19.4. POSITIONING THE ASSEMBLY CAS POSITIONER + 4IN1 CUTTING BLOCK ON FEMUR

**TIP:** Before fixing the CAS positioner on distal block, set the regulation screws in the middle position in order to have the possibility to fine tune the 4in1 block position in both directions.



The distal cutting block must be firmly in place in the same position it was when the distal resection was performed.  
To allow the connection of the cutting block on the CAS positioner, loosen the locking knob (A in the figure above).



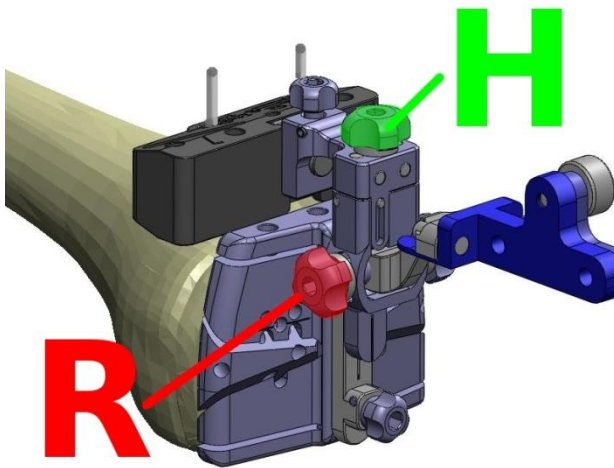
**Pay attention to not reach the complete unscrewing of that knob: it is enough to make only few turns counter clockwise.**

Slide the locking mechanism of the CAS positioner into the slot located on the distal cutting block (B in the figure above). Secure the assembly by turning the knob located on the top of the locking mechanism (A in the figure above).



**Pay attention to not apply excessive torque when screwing the knob (A in the figure above).**

Make sure that the G-array is fully inserted in the appropriate position and using the data provided by the navigator, fine-tune the position of the block (see 16.8).



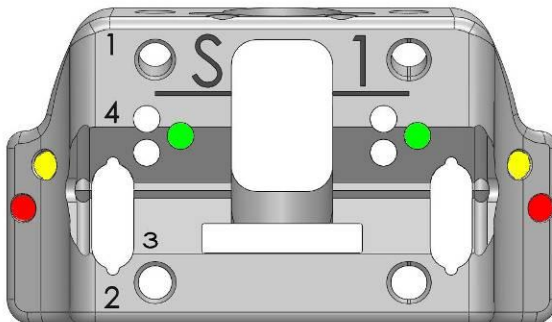
**[CAS 2.637]**

H: Cut height adjustment

R: External rotation adjustment

### 19.5. SECURING THE 4IN1 CUTTING BLOCKS ON FEMUR

After positioning the block under computer assistance (see 17.6) secure it by mean of dedicated pins as shown in figures below.

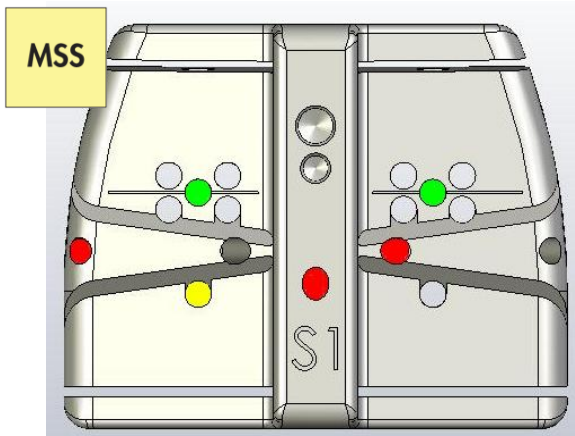


STANDARD BLOCK  
(STD 02.07.10.0201-6)

Green: parallel pins

Red: oblique pins

Yellow: optional pins



MIS BLOCK (MIS 2.631-6) –  
left knee

Green: parallel pins

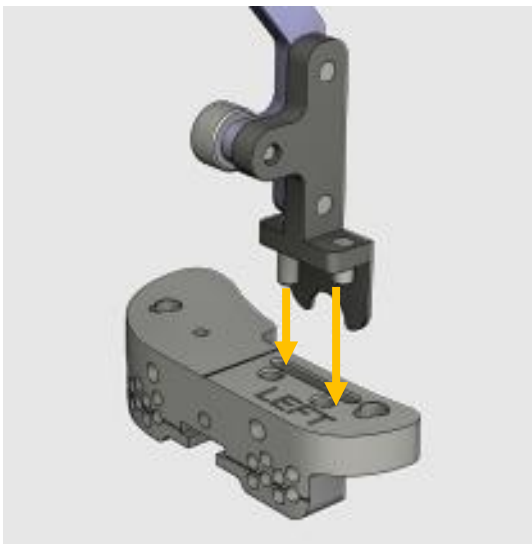
Red: oblique pins

Yellow: optional pin

After the block has been properly fixed, perform the anterior, posterior resections and the chamfers (see 16.10) and finally validate the anterior cut (see 16.11).

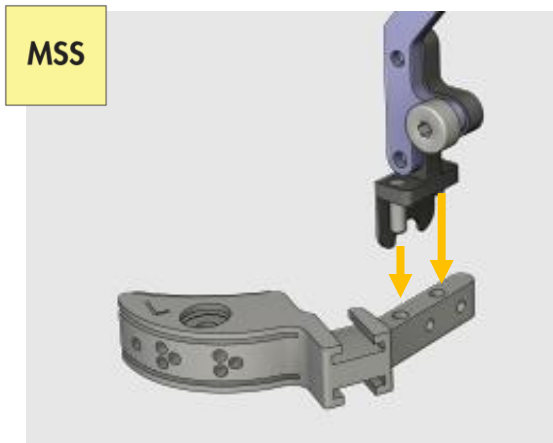
## 20. APPENDIX 3 – OTHER TIBIAL CUTTING BLOCKS

### 20.1. ASSEMBLING THE G-ARRAY ON THE TIBIAL CUTTING BLOCK



#### **[02.07.10.2145-6]**

Select the appropriate cutting block (Left or Right, according to the knee undergoing surgery) and insert the G-array in the two dedicated holes (see fig. left).



#### **[MIS 2.622]**

The same block is used on a left or a right tibia. Orient the block on the appropriate side and insert the G-array in the two dedicated holes (see fig. left).

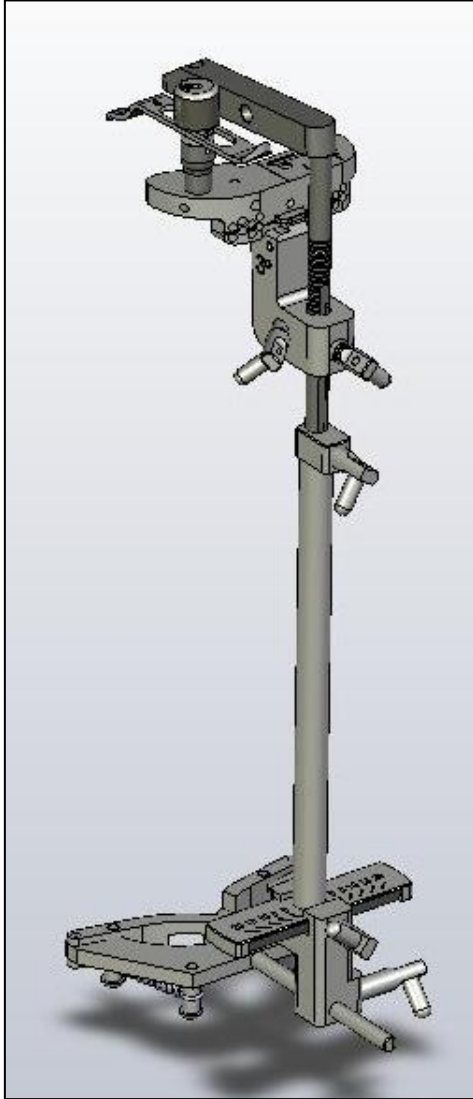


**The tibial cutting blocks STD 02.07.10.2145/6 and MIS 2.622 are not compatible with the fixation by mean of the micrometric positioner.**

## 20.2. ASSEMBLING THE TIBIAL CUTTING BLOCK ON THE EXTRAMEDULLARY JIG

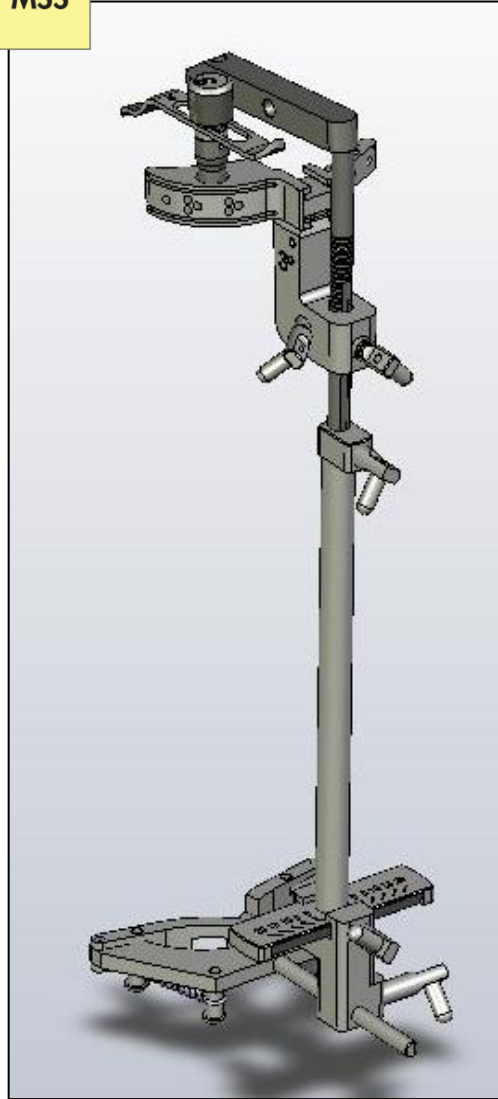
Assemble the tibial cutting blocks on the extramedullary alignment jig as shown in figures below.

**STD 02.07.10.2145/6**



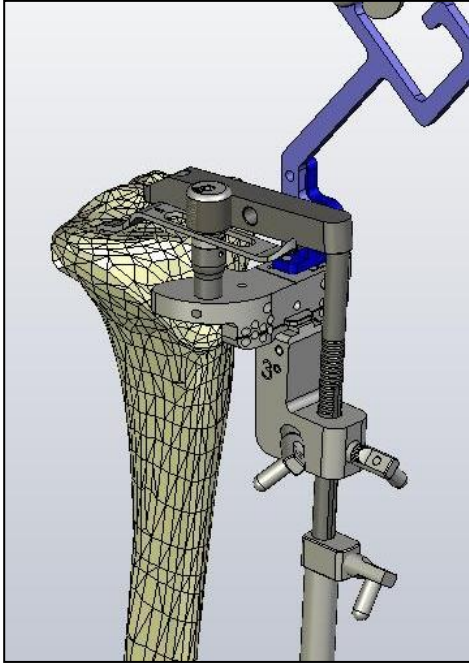
**MSS**

**MIS 2.622**

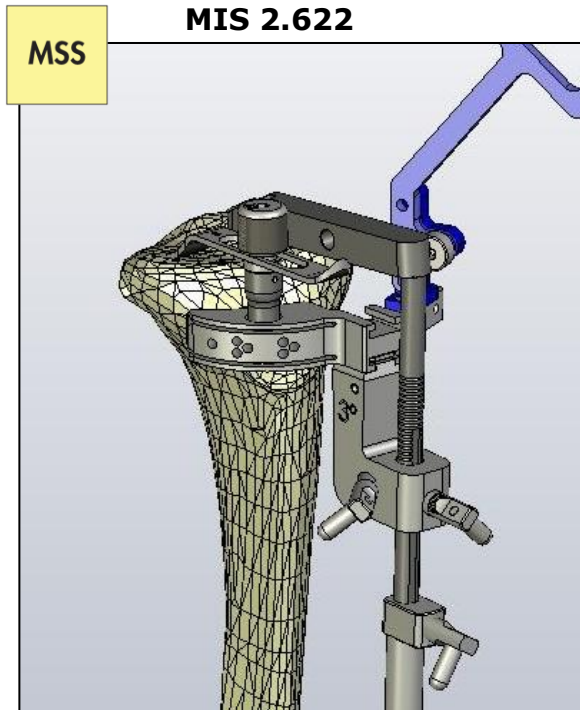


Connect the G-array on the tibial cutting block and then position the assembly on tibia, as shown in figures below.

**STD 02.07.10.2145/6**



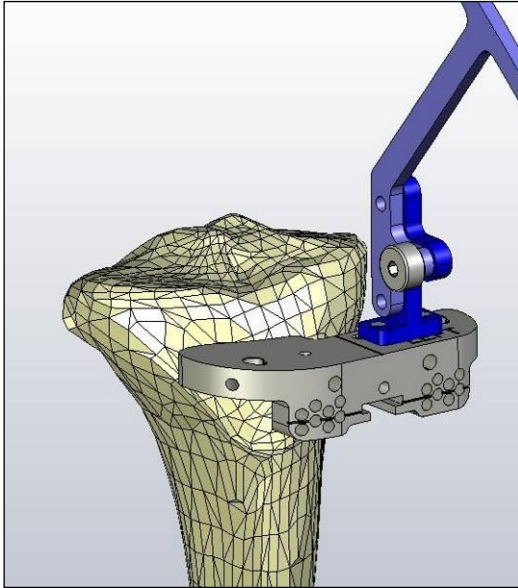
**MIS 2.622**



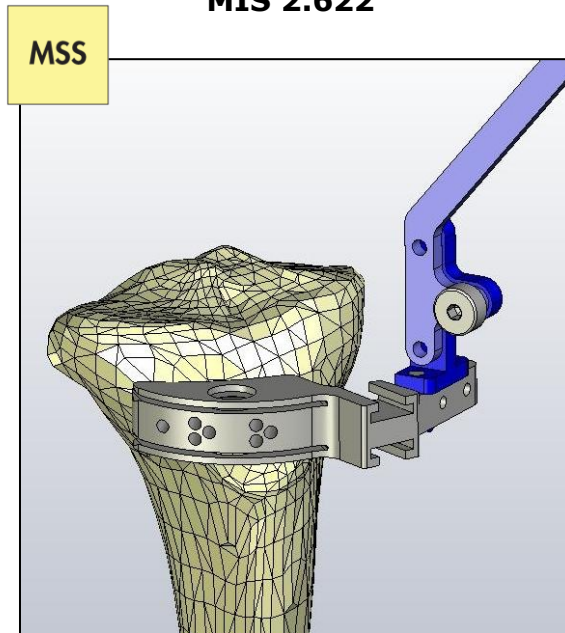
The stylus can optionally be used to estimate the depth of the resection. Under computer guidance it is then possible to fine tune the position of the block.

### 20.3. NAVIGATING THE TIBIAL CUTTING BLOCK FREE-HAND

**STD 02.07.10.2145/6**



**MIS 2.622**

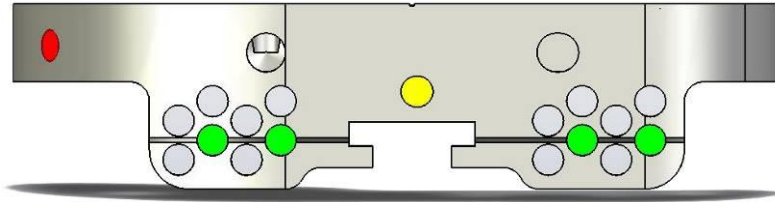


Place the selected tibial cutting block on the tibial anterior face and under computer assistance fine tune its position.

## 20.4. SECURING THE TIBIAL CUTTING BLOCK ON TIBIA

STANDARD BLOCK (STD 02.07.10.2145/6)– left knee

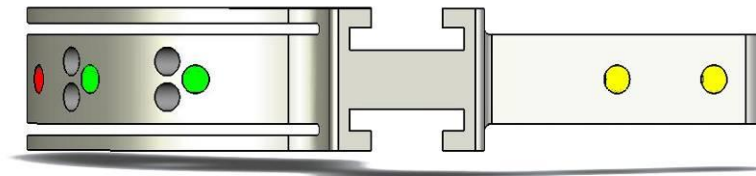
Green: parallel pins  
Red: oblique pin  
Yellow: optional pin



**MSS**

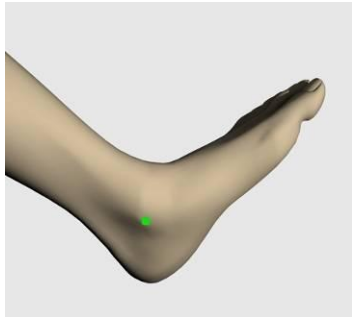
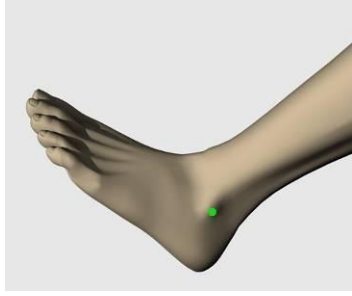
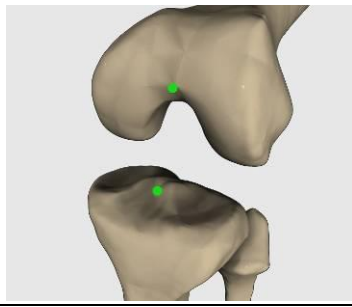
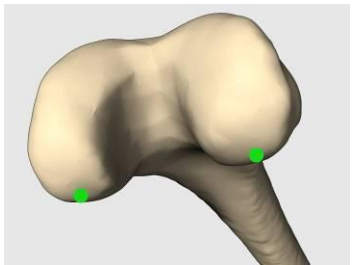
MIS BLOCK (MIS 2.622) – left knee

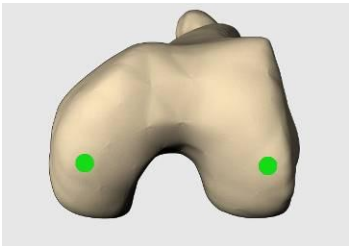
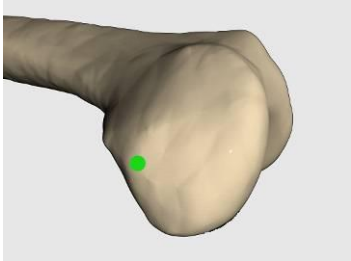
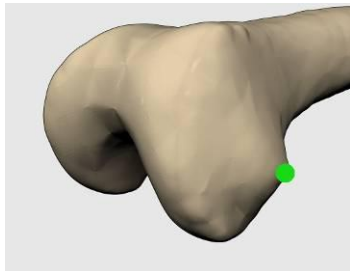
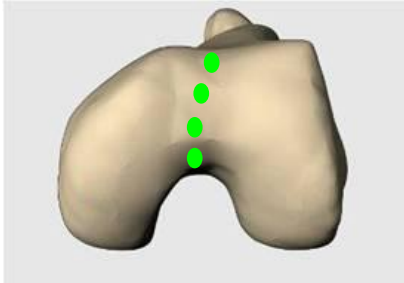
Green: parallel pins  
Red: oblique pin  
Yellow: optional pin



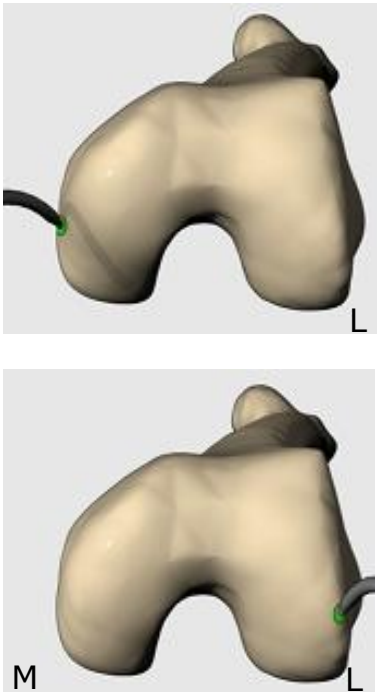
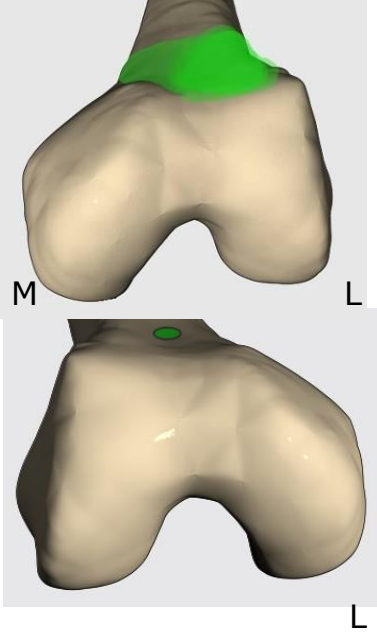
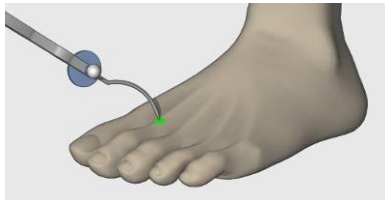
After the block has been properly fixed, perform the tibial resection (see 17.8) and finally validate the cut (see 17.9).

## 21. APPENDIX 4 - ANATOMIC LANDMARKS

| Landmark                  | Description                                                                                             | Picture                                                                              |
|---------------------------|---------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Medial Malleolus          | Most protruding point of the medial malleolus                                                           |    |
| Lateral Malleolus         | Most protruding point of the lateral malleolus (tip of the fibula)                                      |   |
| Tibia Center              | 2 mm anterior to the center of the tibial eminence                                                      |  |
| Femur center              | in the middle of the intercondylar notch, the most distal point of the trochlea                         |                                                                                      |
| Medial condyle posterior  | The most posterior point of the internal condyle –in contact with the tibia when the knee is flexed 90° |  |
| Lateral condyle posterior | The most posterior point of the external condyle –in contact with the tibia when the knee is flexed 90° |                                                                                      |

|                        |                                                                                                                                                    |                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Medial distal condyle  | The most distal point of the internal condyle, in contact with the tibia when the knee is in full extension                                        |    |
| Lateral distal condyle | The most distal point of the external condyle, in contact with the tibia when the knee is in full extension                                        |                                                                                      |
| Medial epicondyle      | The middle of the sulcus (" <i>surgical</i> " epicondylar axis) or the most prominent point ( " <i>anatomical</i> " epicondylar axis) <sup>1</sup> |   |
| Lateral epicondyle     | The most prominent point, in correspondence with the insertion of the collateral ligament.                                                         |  |
| Whiteside's Line       | The deepest line of the trochlear groove.                                                                                                          |  |

<sup>1</sup> The "*surgical*" axis is usually 6° with respect to posterior condyles (Yoshioka et al. – JBJS, 1987); the "*anatomical*" axis is usually 3.5° with respect to the posterior condyles (Berger et al. – Clin. Orthop., 1993).

|                         |                                                                                                                                                                                                                               |                                                                                       |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Medio-lateral reference | <p>The two points will define the maximum acceptable width of the prosthesis. If the selected femoral size of the implant is wider than the distance between the two points a warning message will be displayed.</p> <p>M</p> |     |
| Saw blade exit          | <p>The Navigation System will use the collected points to prevent notching the femoral anterior cortex. Collect one or more points on the area you wish or expect the blade to exit from the bone.</p> <p>M</p>               |    |
| Second Metatarsus       | <p>The landmark that is usually pointed at when checking the alignment of the tibial cutting block using the telescopic alignment rod</p>                                                                                     |  |

## 22. INSTRUMENTS

The following instruments are part of the navigation instruments set:

| Ref. No.      | Description                                          |
|---------------|------------------------------------------------------|
| 33.22.0001    | Femoral rigid body                                   |
| 33.22.0002    | Tibial Rigid body                                    |
| 33.22.0072    | Self-threading pins L 100mm                          |
| 33.22.0071    | Self-threading pins L 125mm                          |
| 33.22.0073    | Self-threading pins L 150mm                          |
| 33.22.0101    | Self-threading pins L 100mm Short Thread             |
| 02.07.10.2299 | Pin D=3.2 L=100 ISO5835-L=25 meche triangle          |
| 02.07.10.2303 | Pin D=3.2 L=100 ISO5835-L=25 meche triangle          |
| 02.07.10.2046 | Pin adaptor – Hudson coupling                        |
| 33.22.0102    | Self-threading pins L 125mm Short Thread             |
| 33.22.0103    | Self-threading pins L 150mm Short Thread             |
| 02.07.10.2281 | Pin adaptor – Hudson coupling                        |
| 33.24.0096    | Navigation sword pin                                 |
| 33.22.0065    | Easy Clip™                                           |
| 33.22.0129    | Femoral Holder                                       |
| 33.22.0130    | Screw guide                                          |
| 33.22.0131    | Drill guide                                          |
| 33.22.0141    | Adaptor for cutting guide rigid body                 |
| 33.22.0049    | Fastening wrench Fixano                              |
| 33.22.0050    | Template for cuts control                            |
| 75.36.302     | Tightening screw with OR for rigid body G on adaptor |
| 33.22.0003    | Assembly rigid body G                                |
| 33.22.0004    | Assembly palpator                                    |
| 75.36.301     | Shielding disk                                       |
| 33.22.0052    | Passive Markers (18 pieces)                          |
| 33.22.0057    | Passive Markers (3 pieces)                           |
| 33.22.0053    | Instruments tray                                     |
| 33.22.0100    | Plate for G calibration                              |
| 33.22.0107    | pins locking clamp                                   |
| 33.22.0108    | head for fixing rigid body                           |
| 2.637         | CAS 4in1 Positioner                                  |
| 33.22.0137    | 4in1 micrometric positioner                          |
| 33.22.0135    | DT micrometric support                               |
| 33.22.0136    | DT micrometric positioner                            |
| 02.06.10.0069 | Bone clamp right                                     |
| 02.06.10.0070 | Bone clamp left                                      |
| 02.06.10.0045 | Bone clamp plier                                     |
| 02.06.10.0014 | Distal micrometrical positioner                      |
| 02.06.10.0004 | Distal cutting block                                 |

|               |                                       |
|---------------|---------------------------------------|
| 02.06.10.0000 | Medial jaw small right                |
| 02.06.10.0001 | Medial jaw small left                 |
| 02.06.10.0002 | Large medial jaw right                |
| 02.06.10.0003 | Large medial jaw left                 |
| 02.26.10.0011 | Universal hex-head screwdriver 3.5 mm |

The following instruments are part of the GMK Instruments set and are mentioned or appeared in this document.



These instruments are part of different GMK instrumentation generations. Some items may have the same description but different reference numbers.

| <b>Ref. No.</b> | <b>Description</b>                           |
|-----------------|----------------------------------------------|
| 02.07.10.0105   | Extramedullary superior guide                |
| 2.617           | Extramedullary superior guide (without pins) |
| 02.07.10.0115   | Tibial resection guide distal part           |
| 02.02.10.0022   | Malleolar clamp support                      |
| 02.02.10.0708   | Spring malleolar clamp                       |
| 02.07.10.2143   | Tibial cutting guide 3° support              |
| 02.07.10.2160   | Tibial Palpator 2mm – Fast coupling          |
| 02.07.10.2147   | Tibial Palpator 8mm – Fast coupling          |
| 02.07.10.2146   | Left Tibial cutting guide                    |
| 02.07.10.2145   | Right Tibial cutting guide                   |
| 02.07.10.0111   | Standard Tibial Left Cutting Guide           |
| 02.07.10.0113   | Standard Tibial Right Cutting Guide          |
| 2.622           | MIS L/R Tibial Cutting Guide                 |
| 02.07.10.0290   | MIS Right Tibial Cutting Guide               |
| 02.07.10.0291   | MIS Left Tibial Cutting Guide                |
| 2.623           | Standard Distal Cutting Guide                |
| 2.618           | MIS Distal Cutting Guide                     |
| 02.07.10.0127   | Standard Distal Cutting Guide                |
| 02.07.10.0065   | MIS Distal Cutting Guide                     |
| 02.07.10.2101   | Femoral cutting guide 4/1- #1                |
| 02.07.10.2102   | Femoral cutting guide 4/1- #2                |
| 02.07.10.2103   | Femoral cutting guide 4/1- #3                |
| 02.07.10.2104   | Femoral cutting guide 4/1- #4                |
| 02.07.10.2105   | Femoral cutting guide 4/1- #5                |
| 02.07.10.2106   | Femoral cutting guide 4/1- #6                |
| 2.631           | MIS - Femoral cutting guide 4/1- #1          |
| 2.632           | MIS - Femoral cutting guide 4/1- #2          |
| 2.633           | MIS - Femoral cutting guide 4/1- #3          |
| 2.634           | MIS - Femoral cutting guide 4/1- #4          |
| 2.635           | MIS - Femoral cutting guide 4/1- #5          |
| 2.636           | MIS - Femoral cutting guide 4/1- #6          |

|                |                                |
|----------------|--------------------------------|
| 02.07.10.0201  | Femoral cutting guide 4/1- #1  |
| 02.07.10.0202  | Femoral cutting guide 4/1- #2  |
| 02.07.10.0203  | Femoral cutting guide 4/1- #3  |
| 02.07.10.0204  | Femoral cutting guide 4/1- #4  |
| 02.07.10.0205  | Femoral cutting guide 4/1- #5  |
| 02.07.10.0206  | Femoral cutting guide 4/1- #6  |
| 02.02.10.0145A | Pins Ø3.2, L 70 mm             |
| 02.02.10.0145B | Pins Ø3.2, L 90 mm             |
| 02.07.10.2194  | Sword pin Ø 3.2 L 22 mm        |
| 02.07.10.2113  | Saw Blade Guide                |
| 02.07.10.0077  | Medium sickle finger           |
| 02.07.10.0054  | Small sickle finger            |
| 02.07.10.2230  | IC reference spacer            |
| 02.07.10.2305  | Tibial cover plate # 1-3       |
| 02.07.10.2307  | Tibial cover plate # 4-6       |
| 02.07.10.4710  | Tibial Spacer - size 1-3 H10mm |
| 02.07.10.4810  | Tibial Spacer - size 4-6 H10mm |
| 02.07.10.1027  | Trial base handle              |